

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
THE MICROBIAL SAFETY OF FRESH PRODUCE

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Malcolm X Branch Library
Multipurpose Room
5148 Market Street
San Diego, California 92114

Wednesday,
May 27, 1998
10:00 a.m.

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P R O C E E D I N G S

(10:00 a.m.)

MODERATOR **VIOR**: May I have your attention?

Hello. Is this on? Great.

Good morning, everybody, and welcome to **today's** public meeting on the microbial safety of fresh produce. My name is Rosario **Quintanilla** Vior, and I am the Public Affairs Specialist for the FDA at the Los Angeles District Office.

What I'd like to do today is welcome you, give you some background, go over the agenda, and some points that you may consider for today's meeting.

In October of 1997, President Clinton announced the Initiative to Assure the Safety of Imported Domestic Fruits and Vegetables, and as part of this initiative, the President directed the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture, and in close cooperation with the agricultural community, to issue guidance on good agricultural practices, GAPS, and good manufacturing practices, **GMPs**, for fruits and vegetables.

The FDA and the USDA have developed a proposed guide that addresses the microbial food safety hazards and good management practices. The draft guidance is intended to assist growers and handlers in examining their operations

1 for potential microbial hazards and in identifying
2 management practice options that may be adopted to minimize
3 the risk of microbial contamination from flesh produce.

4 Last December, we sponsored a series of workshops
5 at grassroots meetings around the country to introduce a
6 working draft of the guide. We will review comments today
7 from those meetings, but today's meeting is intended to
8 continue the process of seeking input on that guidance
9 document.

10 We have the guide in Spanish. For those that
11 would like that copy, it's available at the registration
12 table. This meeting today is being transcribed. We have a
13 transcriber at our left here. I would ask that any of you
14 who ask a question, particularly at the end, when we're
15 taking the public section, would you please introduce
16 yourself so the transcribe can make note of that. And we
17 will have slides in English and in Spanish on both sides of
18 the podium here.

19 **Today's** meeting is structured to maximize the
20 opportunity for you to ask questions and give us input as to
21 the document. We ask that you please ask your questions
22 clearly, and for those of you that prefer to write those in,
23 there is going to be an address noted as to where you can
24 submit those questions or comments, and you can submit them
25 to the Dockets Management Branch.

1 A couple of housekeeping points. The restrooms
2 and phones are out these back doors on my left, and you just
3 keep veering to your left and you will find them. We will
4 be taking a couple of breaks, and the speakers mostly will
5 be available for those of you that would like to ask
6 questions at that time, as well.

7 While this may seem a bit formal up here, **we'd**
8 like to tell you that we want to keep this as informal as
9 possible, so that we maximize the opportunity that you have
10 to dialogue with the folks here,

11 Information packets were provided to you at the
12 registration table. If you have not signed in, please do
13 so. There is a packet available along with today's agenda.

14 Now, going back to that agenda, there is one
15 change that I will make note for you, and that is that at
16 the **11:15** discussion panel, the last speaker, on foreign
17 technical cooperation, was to have been Mr. **Lloyd Harbert**.
18 He will not be with us today, but DeAndra Beck will present
19 that portion.

20 Without adding any more time to this, I would like
21 to introduce this morning's panel and have them address you
22 with some general comments. First, I'd like to introduce to
23 you my boss, my boss' boss, Richard Baldwin, who is our
24 Regional Food and Drug Director for the Pacific Region.

25 \\

1 RICHARD BALDWIN

2 REGIONAL FOOD AND DRUG DIRECTOR

3 PACIFIC REGION, FOOD AND DRUG ADMINISTRATION

4 MR. BALDWIN: You've heard of synchronized
5 swimming, so what we're doing is synchronized standing and
6 walking. This morning I would like to welcome you on behalf
7 of the Food and Drug Administration, in particular the
8 Pacific Region.

9 When I got here earlier, I took the time to walk
10 around and look at some of the photos, and one in particular
11 caught my attention. It's Fason Lowe (phonetic), who is a
12 producer and a director. **He's** over there. The quote there
13 was "Always complete what you start," and I think that's
14 appropriate for what we're doing today.

15 As Rosario mentioned, we had a number of public
16 meetings back in December, and I remember doing something
17 very similar in Geneva, New York, making a welcoming
18 statement and moderating some of the sessions.

19 This is a work in progress. The good agricultural
20 practices were shared back then, and we received a number of
21 comments, and this is another effort to enlist from you your
22 feedback, so that we make this a viable guideline that will
23 be helpful in what I consider the government's business of
24 consumer protection, **at** least the Food and Drug
25 Administration.

1 If someone were to ask me what our bottom line is,
2 I would say that we want to facilitate getting good products
3 into commerce, and getting unsafe or bad products from
4 consumer channels. That's what we're all about today.

5 The revised draft was made available April the
6 14th. The open period for comment is until June the 29th.
7 I encourage you, through this meeting and formally, in
8 writing, if you choose, to give us your feedback, so that we
9 can speak frankly and candidly about the guidelines, and try
10 and make them as viable as possible for all of us.

11 The guidelines are a partnership with the Food and
12 Drug Administration, USDA, sister agencies at the federal
13 and state level, and with the industry. We are partners
14 with the industry. You're stakeholders with what we do, and
15 vice versa.

16 FDA has a daunting task, I think. Twenty-five
17 cents of every consumer dollar that's spent are on products
18 that we're responsible for regulating. When I think of what
19 we're doing today as far as the good agricultural practices,
20 I kind of think of a network. For those of you that are
21 familiar with e-mail, this is part of the network. If we
22 don't have good guidelines, we're not going to be able to
23 get food products from the farm to the table safely. So
24 that's my analogy of what we're all about.

25 President Clinton, back in October, charged FDA to

1 take the lead. We're working with our counterparts in doing
2 that. I encourage you, as Rosario said, to use this as an
3 opportunity. We'll be here most of the day. Some of us
4 have to catch airplanes, but take the opportunity to have a
5 **good** dialogue, to give us your feedback, to help us make
6 this a viable partnership in the best possible guides we can
7 **put** out for you. Thank you.

8 MODERATOR **VIOR**: Thank you, Richard. Next, I
9 would like to introduce you to Terry **Troxell**, who is the
10 Director of Division of Programs and Enforcement Policy --
11 excuse me -- DeAndra Beck, forgive me -- from the Foreign
12 Agricultural Service, U.S. Department of Agriculture.

13 DEANDRA BECK

14 FOREIGN AGRICULTURAL SERVICE (FAS)

15 UNITED STATES DEPARTMENT OF AGRICULTURE

16 MS. BECK: Good morning. I'd certainly like to
17 thank you and my colleagues at FDA for giving me the
18 opportunity to speak here today on behalf of the U.S.
19 Department of Agriculture. We certainly appreciate your
20 interest, and also your participation in this process, in
21 the initiative to ensure that we have fresh fruits and
22 vegetables that are safe for our consumers.

23 The U.S. Department of Agriculture and the Food
24 and Drug Administration have been and will remain partners
25 in assuring the continued safety of our food. Moreover,

1 JSDA is committed to the continued expansion of world trade
2 in food products, and also expanding freer markets
3 worldwide. If we all maximize our comparative economic
4 advantages, we're all going to benefit, including the
5 consumers worldwide who, in fact, want safe food.

6 Of course, it's essential that all of our food
7 safety regulations and guidance, including those being
8 developed for fruit and vegetables, are based on scientific
9 principles, and they're consistent with our international
10 obligations under the World Trade Organization.

11 We intend to continue the dialogue established at
12 earlier briefings and public meetings since the President's
13 initiative came out in October 1997. Today's meeting is
14 another occasion to ensure that we solicit the input of our
15 trading partners into the guidance on good agricultural and
16 manufacturing practices for both domestic and imported food.

17 We look forward to hearing your comments, in
18 particular, on the good agricultural practices guidance
19 document, either today or within the open comment period.
20 We believe that, in continuing our cooperative educational
21 and technical initiatives, we'll be better able to ensure
22 that safety of domestic and imported food. Again, we really
23 appreciate your participation, and we look forward to
24 hearing your comments. Thank you.

25 MODERATOR VIOR: And now with us is Terry Troxell,

1 Director of the Division of Programs and Enforcement Policy
2 for Center for Food Safety and Applied Nutrition, Project
3 Coordinator for the Produce Initiative, Food Safety
4 Initiative of FDA.

5 TERRY TROXELL

6 DIRECTOR DIVISION OF PROGRAMS AND ENFORCEMENT POLICY

7 CENTER FOR FOOD AND SAFETY AND APPLIED NUTRITION

8 PROJECT COORDINATOR, PRODUCE INITIATIVE

9 FOOD SAFETY INITIATIVE

10 FOOD AND DRUG ADMINISTRATION

11 MR. TROXELL: Thank you.

12 For the folks back in Washington at FDA's
13 headquarters, in the Center of Food Safety and Applied
14 Nutrition, I also want to thank you for coming. We
15 recognize how valuable your time is. We really appreciate
16 your coming to share your insights with us. For us, the
17 most important part of the meeting is what you tell us
18 either today or in written comment.

19 The program is also designed to brief you on the
20 content of the produce guide in the broader context of the
21 Food Safety Initiative of which it is a part. Mary **Ayling**,
22 later this morning, will give us a brief overview of the
23 comprehensive Food Safety Initiative which has been designed
24 to tackle the problem at multiple points in the **farm-to-**
25 table food production continuum.

1 What is the problem? People ask, why are we
2 picking on produce? In **my** view, the problem, and what we
3 are picking on, is emerging pathogens. Emerging pathogens
4 are new pathogenic variants of bacteria like **E. coli 0157:H7**
5 which can cause horrible illness in young children. They
6 are pathogens like Salmonella enteritidis, which has
7 developed the capability of infecting the ovaries of laying
8 hens, so that Salmonella are sometimes deposited inside the
9 egg during its formation.

10 Emerging pathogens are also known pathogens like
11 **Cyclospora** which suddenly cause outbreaks in foods or
12 regions where it previously occurred infrequently.
13 Cryptosporidium is another pathogen that has recently been
14 recognized, mostly with drinking water. Globalization of
15 markets, changing production technologies, mass
16 distribution, and vulnerability of an aging and more
17 susceptible U.S. population all contribute to the spread
18 and/or impact of emerging pathogens. The Food Safety
19 Initiative is our response to these microbial challenges to
20 our food safety system.

21 There are at least two themes that have been
22 developing in food safety to redesign our system for the new
23 millennium, to win the battle of the emergent pathogens.
24 One them is cooperation and partnerships. The Fight Bac
25 Consumer Education Initiative is a product of the

1 partnership for food safety education. The Fight Bac
2 character is on the folder that you received today.

3 Check out the Internet site which is identified on
4 the back there sometime. There is a tremendous amount of
5 information, and it's a tremendous program that really has a
6 possibility of making real connections with children and
7 consumers and children to improve -- so that we can get them
8 to do their part.

9 Recently, the Food Safety Training and Educational
10 Alliance was formed for retail food service vending
11 institutions and regulators to optimize resources to deliver
12 retail food safety training. In another cooperative effort,
13 we will be working on a survey of producer and packer
14 practices with USDA's National Agricultural Statistical
15 Service. This survey is intended to help us measure
16 progress in improving practices.

17 These are just a few examples. There will be
18 cooperation of all sorts between national governments,
19 between national governments and state and local
20 governments, between governments and producers, et cetera,
21 all this being facilitated, of course, by the computer
22 communications revolution.

23 The other them is prevention. While prevention
24 was always encouraged, there is a major shift from **lot-by-**
25 lot testing to designing prevention into the production

1 process. This means producers can have higher confidence in
2 meeting their responsibility to produce safe products, and
3 consumers will have more confidence in these products.

4 FDA's Hazard Analysis and Critical Control Point
5 Regulations, **HACCP** for short, went into effect in December.
6 These regulations are seafood regulations. HACCP is a
7 science-based prevention system tailored to each production
8 facility. USDA began phasing in HACCP regulations in 1997
9 for meat and poultry. On April 24th this year, FDA proposed
10 HACCP regulations for **juice**. On April 28th, FDA announced a
11 pilot HACCP program for retail settings. On May 19th this
12 year, USDA and FDA issued a joint advance notice of proposed
13 rule making on safety of shell eggs and egg products from
14 farm to table.

15 We are here today to discuss the broad-scope
16 produce guide to assist producers, packers, and distributors
17 to take affirmative, voluntary, practical measures to
18 prevent pathogens from causing food-borne illness. As YOU
19 can see, the prevention theme recurs in many product areas.
20 Once again, thanks for your assistance in developing the
21 guide.

22 MODERATOR VIOR: Next, we have Mr. Michael
23 **Villaneva**, Program Specialist for the Production Food Safety
24 of the California State Department of Agriculture.

25 \\

1 MICHAEL VILLANEVA

2 PROGRAM SPECIALIST, PRODUCTION FOOD SAFETY

3 CALIFORNIA STATE DEPARTMENT OF AGRICULTURE

4 MR. VILLANEVA: Thank you. Good morning to all.

5 **I** glad you could all make it, and **apprec**:ate you participating
6 **in** this process.

7 I'm going to give you just a little bit of **CDFA's**
8 perspective on this meeting and some of the things that
9 **we've** been involved with. I think it's good that you've
10 turned out, because this is an open process, and I want to
11 **commend** FDA for putting this document together. I think we
12 **all** recognize that there's issues and problems out there,
13 **out**, you know, I'm real proud of what our industry is doing.

14 In terms of an open process, this document has
15 **gone** through a lot of revisions, and I want to, you know,
16 **commend**, again, FDA for allowing, you know, public input.
17 **We** had a chance to go back, **CDFA**, and participate in the
18 **first** draft revisions, and, having been in government for a
19 **while**, I'm pleased to set that the document has undergone
20 some significant revisions. It reads better. It's much
21 more user friendly. And so I'm here to tell you that, by
22 reviewing, analyzing, looking, and getting back, we're **going**
23 to have a document that comes to plate.

24 I think one of the criticisms when the document
25 came out was that there were some areas that weren't

1 science-based. They seemed to be focusing on specific
2 commodities, and we recognized that, and a lot of that has
3 dropped out.

4 The other industries' concerns, and I think **CDFA's**
5 as well, was that there needed to be more understanding and
6 knowledge of what's going on out in the industry, and I
7 speak for some of the associations here in California that
8 have been very progressive and proactive in implementing and
9 designing quality assurance programs.

10 We stress the need for FDA to get out and see
11 what's happening, and, again, they're out here, and over
12 today and tomorrow the next week, they're going to be out
13 doing farm tours, and I think **that's** very critical, because,
14 as I understand it, this is a **living**, dynamic document.
15 It's going to be updated, and the more FDA and staff gets
16 out and recognizes and sees what's reality in the field, the
17 process will work a lot better.

18 so, again, I encourage you to participate, take
19 the opportunity to ask questions, and we're looking forward
20 to a good meeting. Thank you.

21 **MODERATOR VIOR:** Next, we have Jeffrey Farrar,
22 Food and Drug Scientist with the Food and Drug Branch of the
23 California State Department of Health Services.

24 \\

25 \\

1 JEFFREY FARRAR

2 FOOD AND DRUG SCIENTIST

3 FOOD AND DRUG BRANCH

4 CALIFORNIA STATE DEPARTMENT OF HEALTH SERVICES

5 MR. FARRAR: Good morning, and welcome. On behalf
6 of the California Department of Health Services, I'd like to
7 **welcome** you to San Diego, and hope that you'll take the
8 opportunity to provide input into this very important
9 **document**. Regrets from my boss, Stu Richardson, who could
10 not be here today, but very much wanted to express his
11 sentiment that this is a very important document and a very
12 important process.

13 California Department of Health Services views the
14 Food Safety Initiative as a positive step, a set of
15 guidelines to enhance the safety of our food supply. This
16 initiative essentially builds upon efforts already underway
17 in California for a period of about 18 months to two years
18 in developing a set of voluntary guidelines for the **fresh-**
19 cut produce industry. This, too, was a cooperative effort
20 between the industry, state, federal, and local regulators.

21 So, without prolonging the welcome, please take
22 this opportunity to provide as much input as you can, and
23 thanks once again.

24 MODERATOR VIOR : And I would like to call up
25 Michael **Clegg** -- where did you go? -- there you are -- the

1 **Dean** of the College of Natural and Agricultural Sciences,
2 University of California at Riverside.

3 MICHAEL CLEGG

4 DEAN, COLLEGE OF NATURAL & AGRICULTURAL SCIENCES

5 UNIVERSITY OF CALIFORNIA AT RIVERSIDE

6 MR. CLEGG: Thank you. I appreciate the
7 opportunity to say a few words here this morning. I'm
8 **actually** here representing Vice-President Reg Gomez for the
9 **Division** of Agriculture and Natural Resources at the
10 University of California system.

11 I think you might ask, well, why is University of
12 **California** even here? What role does it even have to play
13 **in** this process? And to answer that question, I'll say a
14 **couple** of words about the purposes of the university and its
15 **origin**.

16 The University of California actually traces its
17 **origins** to the **Morrell** Act in 1963, which created the land
18 **grant** university system in the United States, and that
19 system is a federal/state/local partnership. The notion of
20 partnerships in creation of solutions to public problems
21 goes back to the year of the Civil War. We've been, we
22 believe, very successful in playing our important role in
23 that partnership.

24 We have two purposes as an institution. The first
25 is to create the best possible science-based information

1 through our research activities, and the second is to
2 transmit that information to those who need it to solve
3 problems in agriculture, in the environment, and all of the
4 other facets of public policy that the nation deals with.

5 University of California does that by teaching
6 **students**, by training students in research laboratories, by
7 hiring the best faculty in the world, and also by creating a
8 technology transfer system that carries scientific results
9 out to the end users, and this is done through the
10 Cooperative Extension Service, which has farm advisors in
11 every county in the state of California.

12 So we're a science-based organization which does
13 research to create new knowledge, to solve public policy
14 problems, and we then transmit that knowledge to the public.
15 We do this through a partnership with state and federal
16 agencies, and there's no area that exemplifies these kinds
17 of problems better than food safety problems.

18 These demand the best kind of science-based
19 solutions, and in a state like California, with more than
20 250 different agricultural commodities, it requires the best
21 efforts from all of the resources that the state and the
22 federal government have to bring to bear on this problem.
23 So **I'm** pleased to be here to represent the University of
24 California in this process.

25 MODERATOR VIOR: Thank you.

1 I think, with all the formal welcomes and
2 presentations, the one thing you might have picked up from
3 everybody here is that the importance here today is to
4 address your questions, explain the guidance document, and
5 get your feedback, get your comments, and involve you in the
6 process. That is what's critical here, and it's the entire
7 purpose of this meeting.

8 As you've also heard, this is a multifaceted
9 approach in terms of the Food Safety Initiative, everything
10 involving from farm to table, or fork, as some **people** have
11 said. It's education, it's science, it's research, it's
12 regulatory involvement, and it's involving all partners
13 concerned, which is why you have all the representatives you
14 have here today. Please take advantage of that, and ask
15 your questions, and address the folks that you need to ask
16 those questions of.

17 Having said that now, I'm going to return to the
18 part of the program where we now will have the draft guide
19 presentation, and its update on the development, by Terry
20 **Troxell**.

21 MR. TROXELL: We know the slides are set, but we
22 haven't worked them from up here, so we'll have to -- we
23 have slides in both English and Spanish. I did. Is that
24 number one for both, Joyce?

25 UNIDENTIFIED SPEAKER: I'm sorry. What did you

1 say, Terry?

2 MR. TROXELL: Have we hit number one for both?

3 UNIDENTIFIED SPEAKER: Not yet.

4 MR. TROXELL: Sorry. Okay. We set?

5 UNIDENTIFIED SPEAKER: Yes.

6 MR. TROXELL: Okay. Thank you.

7 On April 13th, FDA released for public comment the
8 guidance document entitled "**Guide** to Minimizing Microbial
9 Food Safety Hazards from Fresh Fruit and Vegetables," which
10 we, for short, refer to as "the guide." The guide covers
11 general good agricultural and good manufacturing practices
12 most likely to reduce the risk of microbial contamination of
13 fresh produce in the field/packing facility environments.

14 A little later this morning, in our panel
15 discussion, we will look at relevant aspects of the larger
16 Food Safety Initiative, as I already mentioned, and how the
17 pieces fit together. First, however, I would like to
18 introduce the guidance document and discuss how it was
19 developed to this point, what we expect the next steps to
20 be. I think the guide has come a long way since we released
21 a working draft for comment in November of '97. Later this
22 afternoon, in our section-by-section discussion of the
23 guide, **we're** hoping for the kinds of feedback that will help
24 us continue the improvement process.

25 On October 2nd of last year, the President

1 renounced the Produce Initiative. This initiative is part
2 of the larger Food Safety Initiative. It's an enhancement,
3 **basically**, of the Food Safety Initiative. As part of the
4 **Produce** Initiative, the President directed the Secretary of
5 **Health** and Human Services, namely, FDA, in that context, and
6 **the** Secretary of Agriculture, in cooperation with the
7 agricultural community, to develop voluntary guidance on
8 **good** agricultural and good manufacturing practices for
9 **growing** and packing of fresh fruits and vegetables.

10 Why produce? Why now? Although low, the
11 proportion of food-borne illness linked to fresh produce is
12 increasing compared to other foods. This may be due, in
13 **part**, to an increased consumption of fresh produce in the
14 Us. Public health agencies, as you know, are **encouraging**
15 the increased consumption of produce, and consumers are
16 getting the message. Changing distribution patterns in the
17 global supply now make fresh produce widely available **year-**
18 **round**. Consumer demands also drive development of new
19 products and technology such as fresh-cut produce.

20 In addition, we face challenges from new
21 pathogens, increased surveillance of pathogens, and in
22 vulnerable populations, as I have mentioned this morning.
23 Also , in addition to, obviously, the aging populations, we
24 have a growing population of persons with weakened immune
25 systems, people **who**, for **example**, are on chemotherapy.

1 A few points about the guide itself. The proposed
2 **guide** is a broad-scope document addressing general
3 **principles** common to the growing, harvesting, and packing of
4 nest fresh produce in basically all regions of the U.S. and
5 **abroad.** "Fresh produce" means raw, **unprocessed**, or
6 **minimally** processed fruits and vegetables, including **fresh-**
7 **cut.**

8 The guide is voluntary. It does not impose any
9 new requirements for domestic or imported produce. The
10 **guide** focuses on risk reduction, not elimination. The guide
11 is intended to increase awareness of potential sources of
12 microbial contamination in the field and packinghouse
13 environments, and to provide suggestions for practices that
14 are likely to minimize these hazards.

15 The guide represents generally accepted
16 recommendations based on current scientific knowledge of FDA
17 and USDA, with input from experts and other federal and
18 state agencies. For example, we work closely with staff
19 from EPA and OSHA. The guide will be most effective when
20 growers and packers apply the principles in the guide to
21 their individual operations.

22 The proposed guide contains a list of general
23 principles common to successful food safety programs. Two
24 of these principles are prevention of microbial
25 contamination is preferred over corrective actions once

1 contamination has occurred, and the importance of
2 establishing a system of accountability at all levels of
3 agricultural environment.

4 People have spent many hours designing processes
5 very carefully only to have the whole system fall apart if
6 the process is not delivered. That's why it's important to
7 follow through and assure that your design is executed
8 carefully.

9 One of the first things that became clear to us in
10 drafting the guide, and in other phases of this initiative,
11 **is** how much we do not know. For example, no one knows how
12 much of the contamination of fresh produce occurs on the
13 farm or in the packinghouse.

14 On the other hand, current sound science and
15 knowledge of the pathways by which produce may become
16 contaminated enabled us to set out broad-scope
17 recommendations which, if followed, can help reduce the risk
18 of microbial contamination of fresh produce. Potential
19 hazards cited in the proposed guide are listed.

20 When we began to draft the guide in October of
21 last year, one of the first things we did was to review
22 existing guidance documents developed by industry
23 associations, universities, and state departments of
24 agriculture and public health. The Western Growers'
25 guidance document was obviously one of those. It was well

1 out there, and was a document developed in partnership with
2 many different groups.

3 We relied heavily on those early efforts to
4 develop science-based guidelines that could be applied
5 uniformly across commodities and regions. The first draft
6 guide was reviewed by a broad range of technical experts and
7 a host of federal and state agencies. Subsequently,
8 consistent with FDA's good guidance practices policy, we
9 sought input at a series of public meetings around the
10 country.

11 We, FDA and USDA, held our first public meeting to
12 discuss the content of the draft guide in November '97. We
13 also worked with the produce subcommittee of the National
14 Advisory Committee for Microbiological Criteria for Food to
15 develop a working draft guide.

16 One of the things that I think is interesting is
17 that back in '95, FDA had asked the National Advisory
18 Committee on Micro Criteria to Foods (sic.) to look into the
19 issue of produce, to look in because of the increase in
20 concerns of the outbreaks. So this was already a subject on
21 FDA's mind. I'm not sure whether it was early in '95 or
22 late in '95, but, clearly, this has been something that's
23 been brewing for quite a while, and is not something that
24 has suddenly come upon us as of October of '97.

25 This working draft, dated November 25th, '97, was

1 presented at a series of regional meetings around the
2 country, and at an international meeting in Washington, D.C.
3 The regional meetings were in Grand Rapids, Michigan,
4 Geneva, New York, West Palm Beach, Florida, Heletos, Texas,
5 Salinas, California, and Portland, Oregon.

6 Comments at these meetings from consumer
7 representatives and the agricultural community were captured
8 in hundreds of pages of transcripts. We also received 55
9 Letters from growers, packers, industry associations,
10 academia, and state agencies, containing comments on the
11 work in draft.

12 Comments at the public meetings helped shape the
13 next steps for developing the guide. For example, the
14 agricultural community stressed the importance of their
15 relationships with other federal, state, and local agencies,
16 and the need for these groups to play a significant role in
17 developing the guide.

18 Consequently, FDA invited a group of
19 representatives from state departments of public health and
20 agricultural and other federal agencies to assist in
21 identifying major issues raised by comments and to help
22 revise the guide. These folks gave very generously of their
23 time and knowledge, and Mike Villaneva and Jeff Farrar were
24 among the people that helped us take the next step and
25 reshape this document, make the leap forward to a

1 **wonderful** -- what we think is a good proposed draft that we
2 think we should be able to now, with your comment, develop
3 into a final. Again, the revised guide was revised by a
4 host of technical experts.

F What did the comments say? Most comments agreed
6 with the goal of improving food safety and general concepts
7 of the guide. Some comments expressed concern about
8 specific good agricultural or manufacturing practices. 1'11
9 cover some of these concerns, and our **response**, in more
10 detail in a few minutes.

11 Some comments offered specific suggestions for
12 improving the guide, and we thank you for that. The guide
13 can only be as good as comments received, and that is why we
14 are again asking for your help to improve this document.

15 A number of comments addressed areas other than
16 good agricultural and manufacturing practices covered in the
17 guide, for example, the pace of the guidance document
18 development process and the impact of the guidance on
19 international trade. Because these are important concerns,
20 we will address them in an addendum in the back of the
21 proposed guide.

22 Changes to the guide. Because of the comments,
23 and with the help of our review team, we've made a number of
24 changes in the guide, including changes in tone and format,
25 which we hope will make the guide more useful. We' ve

1 increased the emphasis on the health benefits of increased
2 consumption of fresh produce.

3 The guide recognizes the efforts of industry,
4 states, and universities to promote food safety programs,
5 and the leadership role these groups have played in reducing
6 microbial hazards for fresh produce. With the help of
7 technical experts, **we've** reviewed the recommendations in the
8 guide to ensure they are based on generally accepted
9 scientific knowledge.

10 As I mentioned, some comments expressed concern
11 about specific ag and manufacturing practices. For example,
12 a number of comments questioned the recommendation that
13 growers perform microbial testing of agricultural water when
14 there are currently no established action levels or
15 corrective actions.

16 We revised the proposed guide to recognize the
17 difficulties and limitations of microbial testing for
18 agricultural water. We've shifted our focus to good
19 agricultural practices for maintaining water quality. We
20 also refer growers to local water quality experts for
21 guidance and assistance more specific to their operation and
22 region.

23 In the working draft, we noted that submerging
24 some produce in colder water may result in the
25 internalization of water in pathogens, if present. This

1 **finding** has led to recommendations that, for some produce,
2 **such** as produce with internal air **spaces**, wash water **should**
3 **be** maintained 10 degrees warmer than the produce.

4 Many comments maintained that exposing produce to
5 **warmer** water is inconsistent with the need to remove field
6 **heat**. In the proposed guide, this recommendation has been
7 **narrowed** to tomatoes, which are known to be susceptible to
8 **water** uptake. Recent site visits have shown tomato packers
9 **are** carefully monitoring wash water temperatures.

10 In the manure section, a number of comments
11 questioned the recommendation for at least 60 to 120 days
12 between manure application and harvest without additional
13 research. Some comments noted that the growing season in
14 many regions is less than 120 days.

15 The proposed guide recommends maximizing the time
16 between manure application and harvest. It references the
17 60-day minimum cited by the National Organic Standards
18 Board, and deletes references to 120 days. The guide
19 acknowledges that no one knows how long pathogens may
20 survive in manure or in the field. More specific
21 recommendations may be available as research progresses.

22 Many comments on the working draft expressed
23 concerns about the difficulties of wild animal control. A
24 number of comments noted that control measures may conflict
25 with federal, state, and local animal protection

1 requirements. We've revised the guide to recognize the
2 difficulty of controlling wild animal populations, and the
3 need for growers to comply with other requirements.

4 Nonetheless, heavy concentrations of wild animals
5 may be a source of microbial contamination. Early feedback
6 on the proposed guide indicates that some growers still have
7 concerns about our recommendations. This is the opportunity
8 to help us make this section do what it needs to do, in a
9 reasonable and practical way.

10 There are many other areas we could talk about,
11 but I don't want to belabor the meeting with discussions of
12 changes. So, basically, where are we heading now? We've
13 provided 75 days for comment on the proposed guide.
14 Comments will be gathered at a series of public meetings,
15 which this is the last of the public meetings, and may be
16 submitted in writing to the FDA.

17 During the comment period, FDA and USDA personnel
18 are continuing to visit fields and packing operations to
19 observe current practices and get additional feedback. We
20 anticipate working again with other federal and state
21 agencies to review comments and revise the guide, along with
22 the produce subcommittee of the National Advisory Committee
23 on Microbiological Criteria for Foods.

24 We expect the final guide by October, although it
25 is really a living document. As additional information

1 (No response.)

2 MODERATOR VIOR: Everybody is ready for a break.
3 I think we're due one. We can start our break a little
4 earlier. I would ask -- we're scheduled for a **15-minute**
5 break -- that everybody would return at **11:05**.

6 UNIDENTIFIED SPEAKER: Yes. Because of -- the
7 second -- is longer.

8 MODERATOR VIOR: Okay. Let's move that up to
9 **11:00** o'clock, if I may ask you to. Return here -- again,
10 feel free to talk to the folks up here or anybody else that
11 you think might be able to address some of your questions.

12 If anybody would prefer to address us in Spanish,
13 Mr. Ricardo Gomez back there -- Ricardo, would you raise
14 your hand? We are available to help you out. Thank you.

15 (Whereupon, a brief recess was taken.)

16 MR. BALDWIN: Is Michael here, Michael **Villaneva**?
17 Here he comes.

18 What we'd like to do next is to begin a panel
19 discussion, and the purpose is to try and put in context
20 good agricultural practices in a global sense. The
21 panelists include Mary **Ayling**, who's the Director of Imports
22 in the Los Angeles District in Food and Drug, Jeffrey
23 Farrar, who's a Food and Drug scientists -- you had heard
24 from him earlier -- with the Food and Drug branch in
25 California Department of Health Services, and also Michael

1 **Villaneva**, who is also with the state of California. We
2 have Ricardo Gomez, who's Chief Horticulturist with the
3 Department of Agriculture, and also DeAndra Beck again, with
4 the USDA Food Safety and Technical Service Division.

5 Let me try and frame what we're trying to
6 accomplish now, is to try and give you, in a sense, a broad
7 oversight of how the pieces fit together with the good
8 agricultural practices. It's to examine the importance of
9 the good agricultural practices guides in meeting the board
10 public health goal of improving food safety and reducing
11 food-borne illness.

12 Also, it's to explore the examples of
13 international cooperation and collaboration to reduce **food-**
14 borne illness, because we are a global society, and to
15 discuss models for information dissemination, technical
16 assistance, and education on the good agricultural practices
17 guides.

18 We're going to start with Mary, to give you an
19 overview of the Food Safety Initiative.

20 **MARY AYLING**

21 LOS ANGELES DIRECTOR OF IMPORTS

22 **FOOD AND DRUG ADMINISTRATION**

23 **MS. AYLING:** Thank you. At least we're not
24 swimming, here.

25 I'm here to give you the broad overview, to bring

1 us back into perspective of times long ago, about a year-
2 and-a-half ago, when the President initiated the Food Safety
3 Initiative, and I think all of you have a copy of "From Farm
4 to Table," which is the theme. It's also the copy of my
5 notes today for the presentation, so I'll be flashing at you
6 as much as possible to get this down.

7 The Food Safety Initiative has a very simple goal,
8 and that's reduce, to the greatest extent possible, the
9 incidence of food-borne illness.

10 There are several components of the Food Safety
11 Initiative. One is surveillance, coordination, inspection,
12 risk assessment, research, education, and the guidance, and
13 the guidance is what we'll be discussing most of the rest of
14 the day.

15 Surveillance. What we want to do with
16 surveillance is expand our current surveillance. Most of
17 this is done through CDC, with state and local health
18 departments, and we want to enhance detection of food-borne
19 illnesses. I think we mentioned earlier that we've seen
20 greater incidence of outbreaks. One of the reasons is that
21 we're doing greater surveillance and better surveillance.

22 I think one of the most exciting parts of the
23 enhanced surveillance is the DNA fingerprinting, which we
24 can use to identify a source of the infectious agents. If
25 two people in two very different parts of the country come

1 **down** with the same illness, that can be DNA fingerprinted to
2 associate those two people with the same product, and then
3 **it** can be traced right to the product.

4 This is great, because then we can identify the
5 **source** better, we can hope to figure out what the problem
6 **was**, and we can also not identify or fingerprint at an
7 entire industry, when it's maybe just one processor.

8 Enhanced coordination. We want enhanced
9 coordination between federal, state, and local agencies so
10 that we can improve the containment of outbreaks, and that
11 we can also speak with one voice. To do that, we have
12 developed the FORCE -G-, which is the Food-borne Outbreak
13 Response Coordination Group. This way, we can speak with
14 one voice, so we don't have different agencies talking about
15 different parts of the food-borne outbreak, to give,
16 sometimes, the wrong impression of what we know and what we
17 don't know.

18 Other coordination that we're doing is what you're
19 seeing here today, and that's coordination between FDA and
20 USDA to develop the good agricultural practices, to develop
21 assistance in education for both the foreign and domestic
22 food industries.

23 Next section is inspection, and some of our
24 targets with inspection -- primarily, one of the greatest
25 ones is to enhance food safety in retail establishments. I

1 think most people realize that food-borne outbreaks commonly
2 are traced to retail establishments, and often to consumers,
3 so we're hoping to increase our inspections by using the
4 Food Code across the country, so that we're all looking at
5 the same thing in the same way.

6 Also, we want to increase the use of **HACCP**. Terry
7 mentioned this already. One of our next uses of **HACCP** is
8 with the proposed regulations for fruit and vegetable
9 juices, which also contains regulations concerning warning
10 labels on these products.

11 Risk assessment. Risk assessment will help us
12 identify where to focus our resources so that we can
13 minimize microbial risks to human health, and so that we
14 aren't wasting resources where they don't need to be used,
15 so that we can concentrate our resources, industry
16 resources, educational resources where they're best used.

17 Research. There are many things, and many things,
18 going on in research, which of course we can't get into too
19 deeply today, but some of the areas where we're looking at
20 increasing research is improving detection methods, both
21 with foods, on the foods itself, and at the farm level.
22 There are many illnesses that we've encountered where we may
23 not be able to detect that organism in the food itself,
24 where you can, of course, find it in a person.

25 The next one is we're looking at research to look

1 at the resistance to traditional preservation methods. The
2 foods have changed, the bugs have changed, and we're finding
3 that some preservation methods just aren't working as well
4 as they used to.

5 Antibiotic resistance, same thing with the bugs
6 changing. I think we call them emerging pathogens because
7 they are changing in their habits, I guess, and they are
8 more resistant to antibiotics.

9 I think some of the more interesting things are
10 involved in the intervention strategies, doing research into
11 irradiation, ozone -- well, see, I can't even say that word,
12 so they probably don't want me to talk about this part, but
13 other intervention strategies that we're looking at that
14 will protect foods or prevent further contamination of
15 foods .

16 Last but not least is our education efforts, and
17 we have plans with USDA and other agencies, industry, **local**
18 and state agencies to develop training plans for the
19 transportation industry. We have an alliance with industry,
20 consumers' trade associations, and academia to **share**
21 different kinds of education efforts that we have. We're
22 promoting and incorporating food safety education in the
23 school systems, and we're developing multilingual food
24 programs for food workers.

25 Someday I'm going to get a color slide of this

1 **little** guy, because this is our Fight Bac campaign, and it
2 **is** central to our education campaign. I've noticed, I was
3 **in** Mexico last week, and there is a very similar type of
4 **organism** that's being used for education.

5 Now to bring us back to the reality of today is
6 the guidance development that we're working on together to
7 minimize the risk of food-borne illness and produce of both
8 **domestic** and foreign origin. "

9 We are also going to be talking about imported
10 produce safety with technical assistance to foreign
11 countries, some training modules, and coordination of some
12 non-FDA training networks.

13 For the Food Safety Initiative to be effective, we
14 have to enhance the coordination, we have to work in
15 partnership with other government agencies, and we have to
16 develop public and private partnerships.

17 The last is, again, a **sales talk** on our web site.
18 It's very easy to get to our web site. We have tons of
19 information, not only on the Food Safety Initiative, but on
20 some of the legislation that's been proposed. There are
21 **hyperlinks** to other web sites, and also to **USDA's** web site.

22 Thank you, and we'll answer questions at the close
23 of the panel.

24 MR. BALDWIN: Thank you, Mary. We have a tag team
25 for your entertainment this morning. Jeff and Michael will

1 give you some insights into how cooperative programs can be
2 used to enhance food safety.

3 MR. FARRAR: Thank you. These new challenges that
4 you're hearing about, the terms "emerging pathogens,"
5 "public health **crisis**," "enhanced food **safety**," all these
6 are new challenges that require innovative new approaches to
7 solve these very complex issues.

8 One of the terms you've heard frequently bandied
9 about, and you will continue to hear it, is a very much
10 overused term, but still one that's very necessary for us
11 here in California, and one we believe in very strongly, and
12 that's the word partnership. We have a very strong history
13 here in California of working together with federal, state,
14 and local agencies to develop solutions to problems that
15 arise.

16 The balance that we find with this term
17 "partnership" includes the word "enforcement," partnerships
18 and enforcement. There is a necessity for enforcement.
19 When we see conditions that violate, clearly violate, state
20 or federal regulations, enforcement actions must be taken.
21 However, this does not lessen the desire or the necessity to
22 continue working with the industry to develop mutual
23 solutions to these problems.

24 A couple examples of some efforts here in
25 California that we have underway, partnership efforts. We

1 recently completed a statewide inspection, identification,
2 education, and inspection of all alfalfa sprout growers in
3 California. This was due to several documented, well-
4 documented outbreaks of illness associated with alfalfa
5 sprouts.

6 With the help from the county health departments,
7 and together with the **USFDA** and our state field
8 investigators, we inspected and collected baseline
9 information from approximately 50 sprout growers throughout
10 the state. Legal actions are being initiated against a
11 couple of these sprout growers, and follow-up reinspection
12 have been scheduled for several others.

13 Additionally, a statewide inspection of small- and
14 medium-sized spring mix lettuce processors is currently in
15 progress. We are about halfway through that statewide
16 effort, and again a cooperative effort between the **USFDA**,
17 states, and the county agencies. We'll see that to
18 completion within the next 60 to 90 days.

19 The state has been fortunate to receive a small
20 amount of funding to provide educational efforts for food
21 safety. We are meeting cooperatively with our sister
22 agencies, with the California League of Food Processors, and
23 other industries to develop plans for how best to allocate
24 those resources.

25 **We're** aggressively pushing legislation, pending

1 legislation, to require food safety certification for
2 managers in retail food facilities in California.

3 We're working closely with the industry, the
4 fresh-cut industry and the California Grocers Association,
5 to improve our ability to trace back products implicated in
6 food-borne outbreaks.

7 These and other activities which are too numerous
8 to mention are going on daily here in California. I just
9 wanted to give you a taste for what we are doing. These
10 efforts will continue, and we think the Food Safety
11 Initiative will enhance the efforts we have underway. Thank
12 you .

13 MR. VILLANEVA: Got these slides that -- kind of
14 work from the hip, but -- talk about today -- spend some
15 time talking about -- plants, particularly -- that's the **key**
16 to moving ahead on food safety -- So there's a lot of
17 exciting things happening, and, you know, the **CDFA** is not a
18 regulatory agency in this arena, certainly in the fresh
19 produce arena, but we want to complement what Food and Drug
20 is doing, so we're finding opportunities to partnership, to
21 encourage, to promote, to educate the industry and the
22 consuming public about how safe our produce is.

23 So what I've been doing -- and a lot of
24 involvement working with the industry in trying to encourage
25 them to adopt quality assurance plans, and so we've cut it

1 to kind of a program that we put into place, and I just want
2 to share some of those things with you.

3 When we look at the issues impacting ag, certainly
4 food safety is right at the top, but it's kind of a -- it's
5 a very dynamic process, and a lot of things that are going
6 on impact food safety, either directly or indirectly. These
7 are just some of the issues that come to bear. Certainly
8 international trade -- **we'll** hear some more on that, but
9 that's a looming problem.

10 In California, we have problems with the dairy
11 wastes, and environmental problems, water quality, and of
12 course most of you are familiar that we've had that
13 suspected -- implicated back to dairy operations, and very
14 much concerned about risk assessment. Science-based facts
15 are needed, rather than unreliable assumptions, and we're
16 all worried about urban legislatures, certainly here in
17 California, and water use. There's just a whole raft of
18 things.

19 When we approach the industry, food safety
20 concerns are real. We've had deaths, **E. coli** in apple
21 juice, and outbreaks in spring mix lettuce. So that's the
22 real problem, and you're seeing a shift from concern about
23 pesticide residues to pathogens, and the public is becoming
24 aware of that. They're driving this agenda. So we can't
25 disregard that. Legislation and regulation is very

1 concerned that this be a voluntary program. Let's let the
2 industry step up and do what they're doing, and they'll do
3 it better than having onerous legislation and regulations
4 imposed on them.

5 Next slide.

6 We certainly have to look at the pathogens that
7 are out there. They're real. One of the points I wanted to
8 make here was that the consumer demand is driving the
9 agenda. One thing I think we're concerned about is this
10 whole decision-making process. These things are made high
11 up, and they're public-driven. Oftentimes, it's not
12 scientists making those decisions, it's administrators. We
13 have a lot of policies out there, federal. There's overlap,
14 USDA, FDA. That tends to complicate the process, but what
15 we tell growers is "You, as the vendor or the producer, are
16 going to ultimately be held responsible for the safety of
17 your product. It doesn't really matter what you did or
18 didn't do. **You're** going to have to be held **responsible.**"

19 Next slide.

20 Certainly public health has concerns here. We've
21 got to work hand in hand as -- you know, shoulder to
22 shoulder to solve the problem. They're very much concerned
23 about the emerging pathogens. One thing that's interesting,
24 and that's why we're so excited, and encouraging the
25 industry and the regulators to come out to the field, is to

1 see firsthand how things have shifted.

2 The food production and processing is really on
3 the farm now, and that's created a whole new set of
4 **problems**. They don't have the resources to effectively
5 **regulate** legislation and regulation. So the onus is going
6 to fall back on the industry, and I think we all acknowledge
7 that the public today is not very up to speed on food
8 **safety**, that it contributes to the problem.

9 When we look at -- we approach growers. We say,
10 'You've got to look at the scope of the food chain. It's
11 **not** just harvest, pack, and ship anymore. You have to look
12 **at** it all the way through, particularly when you get into
13 the wholesale preparation and consumption. That's where the
14 **consumer** is ultimately getting your product, and you're
15 **going** to be held responsible for it. So you've got to think
16 **about** things like positive lawn identification and other
17 things that are going to protect you."

18 A point I want to make here is -- and we heard
19 "**HACCP**." That's a term that certainly has application in
20 food processing plants, but from CDFA'S perspective, we're
21 concerned that that becomes the operative term for food
22 safety. I'm pleased to hear that we're talking about gaps
23 in GMPS, and we told the industry that a good **quality**
24 assurance plan is not a **HACCP** plan. It's just
25 identification and implementation of good ag practices. So

1 we're constantly stressing that point.

2 When **we're** trying to sell quality assurance, there
3 are several things that we view as opportunities for
4 success, and certainly timing is everything. If you **haven't**
5 got a plan in place and something happens, you've missed the
6 mark, and you've got problems. Certainly, when we look at a
7 voluntary program, that's the key. We think it has to be a
8 ground-up approach, where the industry buys into it, and I
9 want to commend Western Growers, the Strawberry Commission,
10 and the other trade associations that are very actively
11 pulling together industry support.

12 One of the keys here, too, is that **they've got to**
13 be easily implemented. I think, when we first got started
14 with this process, there were some unknowns, but I think we
15 all know that a grower has to be able to understand and put
16 those to work.

17 Certainly, when you look at some of the cost
18 advantages, I think growers and the ag industry have to see
19 a return on the dollar. **It's** going to take additional
20 funding and expenditure of dollars to make these things
21 work, but we think, in the long run, there's going to be
22 opportunities for marketing advantages, just to use one
23 example of that.

24 Just a little bit about what's going on in
25 California. We're focused on fresh produce here today, but

1 there are several different industries in this state that
2 have gotten QAPs up and running. I just want to make a
3 quick note that our egg industry -- about 90-percent of all
4 the eggs produced in California are covered by a quality
5 assurance plan, and **that's** been very effective in dealing
6 with outbreaks. So that's the kind of advantages I see as
7 the industry moves forwards and adopts these quality
8 assurance plans.

9 The industry has to identify some key issues, and
10 it may have to address these. They need to understand the
11 purpose. They've got to be willing to expend the dollars to
12 put the programs into place. Western Growers is already
13 involved in an education program to set up some basic
14 curriculum so that workers in the arena can get trained, and
15 that's part of the process. Setting standards comes about
16 from that.

17 One area that I'm very interested from CDFA 'S
18 perspective is verification. We think, as these programs
19 develop and take off, there's going to be a need to have
20 verification. I'm not sure if that's going to be third
21 party or private sector individuals, but it is going to
22 come.

23 Finally, I think, a final selling point is a good
24 program provides a range of benefits. Certainly it allows
25 you to review and to audit your entire operation, and I

1 think a very important part of that is it makes you aware of
2 the potential risks that might come about in your
3 **production/ag** practices.

4 I think a key here is taking credit. I think at
5 least I speak for California. Our industry has done a lot
6 of good things. I don't think they've gotten all the credit
7 that they deserve and should be credited for. So a QAP
8 allows you to that, and certainly a verification process
9 that shows you're addressing problems and making the proper
10 changes is going to protect you.

11 Finally, to conclude, if you've got a good
12 program, you're going to be able to provide the
13 documentation and evidence that your product was produced in
14 a safe and wholesome manner, and that's really the key. So,
15 to kind of tie back with what Jeff mentioned, this is what
16 our partnershiping is all about. It's using Food and Drug
17 to help identify the risks, help hand in hand, and we're
18 real excited about what's happening here in California.

19 MR. BALDWIN: Ricardo is going to help us
20 understand how we can take present infrastructures that we
21 have available in the extension services and expand the
22 capabilities there to get the information out to the people
23 that need to know.

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1 RICARDO GOMEZ

2 CHIEF HORTICULTURIST

3 UNITED STATES DEPARTMENT OF AGRICULTURE

4 MR. GOMEZ: That's quite a chore you gave me. I
5 don't know if I can do that, but let me first give you a
6 feeling for what USDA is. USDA was reorganized a while
7 back, a few years back, and what happened was that agencies
8 with more or less the same type of mission were put together
9 in one group. The agency that I belong to, the Cooperative
10 State Research, Education, and Extension Service, **CSREES**, is
11 part of a missionary -- the research, education, and
12 economics -- and the Agricultural Research Service belongs
13 in that. The National Agricultural Library, which is part
14 of ARS, also is involved. The Economic Research Service is
15 involved, and Terry **Troxell** mentioned the National
16 Agricultural Statistical Service. That is also part of the
17 agency.

18 Originally, the Agricultural Research Service was
19 to do high-risk ag research, and our group of -- our agency
20 was to do the practical part. **That's** changed a little bit.
21 We both do those things, but that's the way it went. My
22 agency is the agency that is linked to the land grant
23 system, and that is a system of over 120 institutions
24 throughout the United States and territories that have the
25 experiment stations and the extension service.

1 So we have a presence, basically in each and every
2 county in the U.S. We have the know-how, the research
3 capabilities to not only do federal work, that is,
4 nationwide, but we also come down to the local level, and
5 California is one of the better examples of research being
6 done at the local level.

7 One of the things that we have taken very
8 seriously, both at FDA and USDA, is the word "initiative."
9 The word "initiative," to us, means you need to focus on the
10 problem. We at the USDA and FDA have redirected and
11 requested additional funds to work on food safety, and food
12 safety of fresh produce. So we are going to do additional
13 stuff to get along and hurry this process up a little bit,
14 or quite a bit.

15 One example that I want to give you, and Doctor
16 **Troxell** mentioned it also, is that we really don't know lot
17 about -- and I'll put manure on the table -- a lot about
18 manure. We do know a lot about manure and its relationship
19 to the organic matter and fertility of the soil. We know a
20 lot about it. But we do not know much about its
21 microbiological problems with foods that we consume. We
22 have redirected quite a bit of our resources to deal with
23 this issue, and we have requested additional funds for **FY**
24 '99. So we are doing additional work.

25 One of the things that our agency does -- and our

1 **agency**, the agency that I belong to, there's only about 300
2 to 400 of us in there, but we're the federal partner, and
3 the whole system has about 20,000 professionals out in the
4 field. So we do get to everybody.

5 We have several programs ongoing, expanded food
6 and nutrition -- and we must acknowledge, and we **have, all**
7 of us, that this food safety problem is not only with the
8 producer. It's a problem that is a whole continuum from the
9 farm to the table. But we have the expanded food and
10 nutrition program, which **deals** with nutritional habits of
11 individuals, to improve them. We can incorporate food
12 safety materials into that. We **don't** need to reinvent the
13 wheel. We don't need, necessarily, to create new programs.
14 We can incorporate in a lot of our ongoing programs.

15 Some of you may be familiar with the pesticide
16 applicator training programs, with the integrated pest
17 management programs that have been so very successful. We
18 can definitely incorporate some of the food safety concerns,
19 water quality, into those programs, and not spend additional
20 time and efforts in creating other programs.

21 One of the things that we must do, and we are
22 doing, and we will continue to do, is to work with industry.
23 We realize and we know that if we **do** not work with industry
24 groups, with producers, we're sunk. We're not getting
25 anywhere. We need their help, and we need their help in

1 several ways. One is to reach as many people as possible,
2 and the other one is for them to tell us what kind of
3 information is lacking, what we need to research in order to
4 do a better job. We must work with industry, and we will.
5 We have so far.

6 I am a member of a group at USDA and FDA that has
7 been appointed to deal with outreach and educational efforts
8 on the fresh produce issue. Industry is a participant in
9 that, a very strong partner. One of the things that we must
10 do is learn from industry what kind of programs they have at
11 the field level, and there are many, so that we don't
12 duplicate the effort that has already been done. We need to
13 utilize our funds creatively, and with the industry help, we
14 think we can.

15 I do want to leave you with a message, though, if
16 nothing else, is that it is greater risk to our health as
17 individuals not to eat produce, fresh fruits and vegetables,
18 than it is the risk of contamination. So keep eating your
19 fruits and **veggies**. We'll all be the better for it. And
20 eat a lot of them. Thank you.

21 MR. BALDWIN: DeAndra is going to give us some
22 insight into the international aspects of technical
23 cooperation, and we might want to turn the air conditioning
24 back on, because we might lose some folks, because I feel
25 it's getting warm in here, and since we have the

1 microphones, I think we can talk over the noise.

2 MS. BECK: Can you all hear? Is this all right?

3 Okay. Great.

4 Well, I think that Rick did a good job of
5 explaining that USDA is involved in this initiative on many
6 different fronts. Many of our USDA agencies have been very
7 active in this whole initiative, from every component, to
8 the monitoring surveillance, to research, to outreach, and
9 there is an important component of this initiative for which
10 my agency is involved, and that is the international
11 component.

12 What I'd like to do is start out telling you a
13 little bit about the Foreign Agricultural Service, and then
14 I'd like to talk to you about some of our programs that we
15 work with international partners on, because, you know, I
16 think we can all say that our agriculture knows no borders
17 at this point.

18 We're very dependent, in the U.S., on our exports,
19 and we're also very dependent, as consumers, on our imports,
20 and so I think the partnerships, again, reach not only
21 within our USDA agencies, within our U.S. government
22 agencies, but they also extend to our foreign partners, our
23 near neighbors and those who are not quite so near.

24 So what I'd like to describe first is that the
25 Foreign Agricultural Service really has two missions. We

1 work with the U.S. agricultural community to facilitate
2 trade and export of U.S. products, but we also have a very
3 large component of activities and commitment to working with
4 foreign producers, processors, governments, et **cetera**, to
5 improve global food production, and processing and
6 distribution.

7 FAS is a principal liaison, if you **will**, for the
8 international partnerships that USDA agencies are involved
9 in, including food safety, and we really span the spectrum
10 of USDA's responsibilities in terms of these links. We work
11 closely with our regulatory agencies, such as the Food
12 Safety and Inspection Service. We also work with our
13 marketing agencies, such as Ag Marketing Service, and we
14 work with our technical agencies, such as the Agricultural
15 Research Service, and we ensure that our technical agencies
16 are very involved in our international cooperative programs.

17 A little bit about FAS. We have staff in
18 Washington, and we also have staff overseas, in embassies
19 and consulates. There are 63 posts overseas that have FAS
20 staff, and, in addition, we have 12 agricultural trade
21 offices around the world. The posts overseas are staffed
22 both by U.S. and by foreign service nationals, who, in fact,
23 represent a lot of the Department of Agriculture's interests
24 overseas.

25 Now , AFS is the acronym for Foreign Ag Service,

1 and if I slip into Washington acronyms, forgive me. It's a
2 little more efficient, however. FAS does have partnerships
3 with many of the agricultural private sector groups across
4 the world, and, for example, since the 1980s, FAS has worked
5 closely with produce industries in the U.S. and Latin
6 America, Caribbean countries, and Asia to promote concepts
7 of quality grade and standards, and to develop and to
8 implement post-harvest treatment technologies, and also to
9 demonstrate improved packaging and distribution for traded
10 fresh fruits and vegetables. We really feel that these
11 years of cooperative efforts are going to be invaluable in
12 working with both domestic and foreign industry to address
13 these food safety issues.

14 Now, if I could have the next slide, please. Put
15 the -- up. There you go. Okay.

16 Now, what I'd like to do is to explain the types
17 of programs that FAS, the Foreign Ag Service, is involved
18 in, and, again to reemphasize, many of the speakers up here
19 have made note of that. We cannot do what we do without
20 having the partnerships that we have with the land grant
21 universities, with other U.S. agencies, U.S. government
22 agencies, as well as USDA agencies, and industry has been a
23 strong supporter of what we're trying to do overseas.

24 We implement international food safety-related
25 programs really under four general areas of cooperation that

1 are listed here. Our training and technical assistance
2 efforts overseas -- I think a good example that some of you
3 might be aware of is our **Cochran** Fellowship Program. Many
4 folks have been very gracious hosts to the foreign visitors
5 that we bring, to really have an idea of what our
6 agricultural system is here in the United States. Over the
7 past three years, the **Cochran** Fellowship Program has
8 provided food safety and also sanitary and phytosanitary
9 training to over 120 participants from 35 different
10 countries.

11 The Foreign **Ag** Service also works very closely
12 with a partner such as the U.S. Agency for International
13 Development, AID, and also the multilateral development
14 banks, such as the World Bank, the Inter-American
15 Development Bank, and the Asian Development Bank, to provide
16 USDA technical expertise, training, and consultation on
17 various initiatives related to food safety worldwide.

18 The second area that we've been very involved in
19 recently is in the data management side, and with the number
20 of foreign visitors that we have coming to the U.S., we
21 would like very much to know what their interests are, and
22 be able to provide them with the kind of training and
23 exposure to our regulatory and technical and production
24 systems that we can. So we've been very involved in working
25 other agencies such as the Animal, Plant, and Health

1 **Inspection** Service, **APHIS**, to put together training videos
2 and training courses that are effective at meeting those
3 needs.

4 The third area that we're very involved in is our
5 international cooperation and research. Now, we administer
6 numerous programs in this area, particularly regarding food
7 **safety**, both USDA-funded and externally funded programs. We
8 have programs in over 20 countries worldwide, and these
9 research initiatives address food safety topics, and this
10 has a very high priority in the criteria for development of
11 the proposals for cooperative research. We really feel like
12 there's a lot of technical expertise that lies beyond our
13 geographic boundaries for which we'd like to take advantage
14 of in the area of promoting our worldwide understanding of
15 food safety issues.

16 I'd also like to mention the cooperation that we
17 have with international organizations. I mentioned earlier
18 that APHIS and FSIS and other agencies are very active in
19 harmonizing sanitary and phytosanitary standards by working
20 with many of the official multilateral standard-setting
21 bodies. Examples are the Codex **Elementarius**, the Office of
22 International Epizootics, and the International Plant
23 Protection Convention of the United Nations Food and
24 Agricultural Organization. Again, the harmonization of
25 standards and regulations worldwide is critical to

1 facilitating an open and free trade across borders.

2 These initiatives are helping us to ensure that
3 imported products are safe for U.S. consumers and that our
4 international trading partners understand the U.S.
5 regulatory and policy framework relating to food safety.
6 Moreover, it helps our U.S. scientists and technical
7 expertise (sic.) gain access to the most current
8 technologies, as I mentioned before. Some of these programs
9 are funded by USDA. Others that are very heavy into
10 technical assistance and cooperation we rely on funding from
11 our development agencies, such as AID.

12 Now, the next slide, please.

13 I'd like to just highlight some of the issues that
14 are being discussed in terms of priorities for technical
15 cooperation on an international basis. I am part of a
16 working group, as is Ricardo. It's an international working
17 group related to the Food Safety Initiative, where we are
18 working to meet the needs of our trading partners, as well
19 as our own needs, in conveying this information worldwide.

20 A couple of the ideas that we have been striving
21 with are targeting some of our efforts. What we'd like to
22 do is increase awareness of how the Food Net system works,
23 which is the state-of-the-art system for identifying and
24 tracking sources of food-borne illness outbreaks, and I
25 think one of the speakers this afternoon may go into more

1 detail. We look forward to sharing the experiences that
2 we've had with developing and implementing Food Net.

3 The second area that we'd like to focus on is
4 improving our risk assessment methods for microbial
5 contaminants. We found that our knowledge base is growing
6 quite rapidly with respect to the food safety risk issues,
7 particularly for seafood, meat, and poultry. Nonetheless,
8 methods of assessing the risk of microbial contamination on
9 produce continue to evolve, and really do need further
10 evaluation.

11 The third area that we'd like to concentrate in is
12 improved risk communication. A recent study by Doctor Tom
13 Hoban at North Carolina State University was conducted on
14 looking at consumer attitudes toward biotechnology, and,
15 interestingly, as a part of the study, Doctor Hoban listed
16 other sources of potential concerns to consumers.

17 The first series of studies was done 1995 through
18 1997, here in the U.S.

19 In fact, could I have the next slide, please.

20 I think the results of these are quite
21 interesting. As you can see, given the issues of concern
22 over pesticides, biotechnology, microbial contamination, by
23 far, consumers in the U.S. were concerned about microbial
24 contamination of their products. This same survey was done
25 in 1995, and is now being updated in Europe.

1 If I could have the next slide, please.

2 Again, with a list of variables to choose from,
3 **microbial** contamination from pathogens was number one
4 concern in Europe.

5 What we'd like to do is to find out the best means
6 by which government can raise public awareness on emerging
7 issues of public health concern without unnecessarily
8 eroding the confidence in the overall safety of our food
9 supply, which, as Ricardo said, and I'll second, I think
10 that we have very strong reason to believe that we have a
11 very, very safe food supply here in the United States.

12 It is certain, as our detection and surveillance
13 systems improve, that we're going to find more incidence of
14 microbial contamination, so it's imperative for us to
15 continue to communicate to our domestic and international
16 consumers the levels of comparative risk.

17 The fourth area --

18 If you could go back to overheads, to the one
19 prior to that.

20 The fourth area that we're interested in is to
21 facilitate the development of international guidelines,
22 recommendations, and standards. We are confident that a
23 harmonized transparent set of international guidelines,
24 recommendations, and standards will achieve a proper balance
25 between public health objectives and the desire to

1 MR. BUNIN: Hi, everybody. I'm Don Bunin from
2 Warwick International Limited. You can tell by the
3 "Limited?" it's an English company, English specialty
4 chemical company. I, as an individual, and the company I
5 represent are a brand-new -- industry, so the comments and
6 questions I'm going to have, as somebody with a strong
7 environmental background, who lived through the whole
8 development of environmental regulations and so on that
9 apply to the chemical manufacturing industry and the
10 chemical using industry -- just an overall reaction. While
11 what we went through is very complex, what you folks are
12 tackling makes what we did look like apple pie.

13 Okay. A couple questions for the panel. Again,
14 as a newcomer, what is the difference between the FDA's
15 responsibilities in this area and USDA's -- you know,
16 frankly, just listening for the first time, it sounds like
17 there's a lot of overlap -- and as that applies specifically
18 to this area of fresh produce? Instead of overlap, it's
19 truly what we've been talking about, is partnership. We're
20 doing it together, and we're doing it together because,
21 number one, we were charged to do it together by our boss,
22 President Clinton, and we're actually doing it together
23 because it's working better together. Instead of being
24 concerned about duplicate programs or overlapping, we're
25 just working on it together. Because we both have different

1 **audiences**, constituents that we work with, we're trying to
2 **cover** a broader picture this way, and **also EPA, OSHA,**
3 **Department** of Labor. There are other agencies that we're
4 **also** working with, in addition to all of the states, the
5 **land** grant universities. Does that make sense?

6 MR. GOMEZ: Let me add something to that before we
7 **get** to your next question, if I may. We have an integrated
8 research plan that is jointly developed by governmental
9 **agencies**, FDA, USDA, EPA, and so on. So **it's** a joint plan
10 that each has a particular piece to develop. There is some
11 **overlap**. That's why we're talking to one another, so that
12 **there** is the least amount, but we have **joint** programs that
13 **are** integrated.

14 MR. BUNIN: Are you all -- does each agency come
15 from a different area of expertise and responsibility as it
16 applies to the industry, you know, before all these joint
17 efforts were set up?

18 MR. BALDWIN: Yes. Congress has charged us with
19 different roles and responsibilities. What we're doing is
20 to try to coordinate that so that we put the network
21 together in a way that facilitates the entire process,
22 because Congress is our board of directors, and they've
23 given us certain requirements, and a legislation they've
24 asked us to implement, and that legislation is different in
25 the sense of, you know, what our different roles are, but we

1 still have to talk to each other, because **we** can't do our
2 jobs effectively if we're not cooperating.

3 MR. GOMEZ: Yes. We definitely have different
4 mission areas, missions to -- but we are working together on
5 that.

6 MR. BUNIN: I guess it's outside the scope of this
7 meeting to carry that any further. As far as the
8 international situation, what areas of the world and/or what
9 countries are the recognized leaders in this field? There's
10 a nice one for you.

11 MS. BECK: Well, if you're talking about specific
12 to fruits and vegetables --

13 MR. BUNIN: Yes.

14 MS. BECK: -- typically, we see a huge amount of
15 expertise, of course, residing here in the United States,
16 Western Europe, Australia, but then there are pockets of
17 excellence worldwide that, in fact, that we're reaching out
18 to tap into. We have cooperative programs in Latin America,
19 Central America, Asia, with our Central European
2a counterparts. We have some very interesting programs in
21 Poland and Hungary. So sometimes it's scientist-driven.
22 Other times, systematically, we see some advances, the U.K. ,
23 Germany, Australia, as I mentioned.

24 MR. BUNIN: Thank you.

25 MR. BALDWIN: Are there any other questions?

1 (No response.)

2 MR. BALDWIN: If there are not, what I'd like to
3 do is to break in a minute or two for lunch. We have fliers
4 on the registration table that will clue you to some
5 restaurants in the area. What I'd like to do is to take an
6 hour for lunch, and try and be back here promptly at
7 1:00 o'clock. Thank you.

8 (Proceedings recessed from 11:50 a.m. to 1:00
9 p.m..)

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AFTERNOON SESSION

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1
2
3 MR. BALDWIN: Werre going to get started again
4 low , if you could take your seats. This afternoon's session
5 is an in-depth discussion of the guidance document, and I
6 thought I'd just take a minute to introduce Joyce, because I
7 met Joyce in December, on the other side of the country, in
8 Geneva, New York, and, as I mentioned this morning, as I was
9 walking around looking at some of the photos and some of the
10 exhibits, there is some real art work here in the exhibits,
11 and Joyce is really an artist, too, because she's the person
12 that kind of crafts the guidelines.

13 So you're going to get an opportunity to talk to
14 the artist who is crafting the work in progress. Again,
15 take this as an opportunity to have a dialogue, when it's
16 appropriate to ask Joyce what, exactly, is meant by some of
17 the things that are in the guidance document. Joyce is a
18 Consumer Safety Officer in the Center for Food Safety.

19 I'm not going to spend any more time up here. I'm
20 just going to turn the podium over to Joyce.

JOYCE SALTSMAN

CONSUMER SAFETY OFFICER

FSI, CFSAN, FOOD AND DRUG ADMINISTRATION

24 MS. SALTSMAN: Good afternoon. I hope we can keep
25 this discussion going so you all don't get too sleepy after

1 **having** such a wonderful lunch. Let me see if I can -- okay.
2 [f we could turn the lights out .

3 Okay. All right. As you know, the source -- I'm
4 **going** to divide my talk now into the sections that are
5 **covered** in the guidance document, from water, to manure in
6 **biosolids**, into worker health and safety, and then into
7 **field** and facility sanitation, transportation, and then
8 trace-back.

9 If you have -- when I finish the section, I'm
10 going to stop and see if you have any comments you'd like to
11 make. I would appreciate it if you would direct your
12 comments to the topic of the guidance document, in terms of
13 asking for clarification or making suggestions on how we can
14 improve it, because we really want this to be a working
15 session, and not just to present the guide and say, "Here it
16 is." We want to get feedback from you, and we really
17 appreciate you all coming for that purpose.

18 Now , we know that the source and quality of water
19 will dictate its potential for being a carrier of pathogenic
20 organisms, many of which are shown on this slide. Water may
21 be a direct source of contamination, or it may be an
22 indirect source of contamination when the water itself
23 carries organisms that are spread, perhaps, to the field or
24 packing facility.

25 Even small amounts of pathogens can cause illness.

1 No one knows what proportion of contamination on fresh
2 produce is due to water use in the field or packinghouse.
3 Further, many neighbors have to share a watershed.
4 Operators may have limited control over activities outside
5 the boundaries of their own properties. However, the
6 guidance document urges them to be proactive, to minimize in
7 those areas over which they might have some control.

8 A general guideline to consider for agricultural
9 water is that the water quality should be adequate for its
10 intended purpose or for its intended use. The potential for
11 contaminating produce depends on many interrelated factors,
12 such as the degree of contact, time between use and harvest,
13 and the physical characteristics of the crop.

14 Growers are encouraged to identify their water
15 sources and assess the potential for contamination. Some of
16 the many different water sources used by growers are shown
17 here. In general, groundwater, such as deep wells and
18 municipal supplies, is less likely to be exposed to high
19 levels of pathogens, compared to surface waters.

20 These are some general guidelines to maintain
21 water quality. Growers should be aware of current and
22 historical land use, and potential sources of microbial
23 contamination related to that use. On-farm sources of
24 contamination may include runoff from leaking or overflowing
25 manure storage lagoons or livestock access to surface waters

1 or pump areas. Growers are encouraged to follow good
2 agricultural practices to reduce or eliminate obvious
3 sources of contamination. Soil conservation practices are
4 one way to help protect water sources.

5 Now, that section -- this slide ends the section
6 on agricultural water. I'm going to begin on processing
7 water, but I will now like to have any comments you'd like
8 to make on this section, on agricultural water.

9 (No response.)

10 MS. SALTSMAN: Okay. **We'll** move on. A general
11 guideline mentioned with agricultural water also applies
12 with processing water, and that is that the water quality
13 should be compatible with its intended use. As the degree
14 of water to produce contact increases, water quality also
15 needs to increase. Treatments towards the end of
16 processing, such as the final rinse, may require higher
17 water quality compared to earlier operations such as water
18 that is used in dump tanks.

19 In general, water that meets the microbial
20 standard for drinking water would be considered safe and
21 sanitary. Water needs to be safe and sanitary for its
22 intended use not just at the beginning of a process, but
23 throughout the process. If water is recycled, it should be
24 countercurrent to the movement of the produce through the
25 unit operations.

1 The main point here is that, although water
2 quality needs may vary, water should never contribute to the
3 food safety concerns.

4 Good manufacturing practices to help maintain
5 water quality would include periodic microbial testing,
6 monitoring PH and antimicrobial levels, if antimicrobial
7 are used, and changing water or adding back water or
8 overflow as necessary to the process.

9 Packers should routinely clean water contact
10 surfaces and equipment to remove debris, plant material, as
11 necessary. They should also routinely inspect and maintain
12 water quality equipment, such as the filters, backflow
13 devices, chlorination, chlorinators -- chlorine injectors,
14 excuse me -- and so forth.

15 Sanitizers or antimicrobial in processing water
16 may be useful in some operations for reducing both the
17 pathogens on the surface of produce and for reducing
18 pathogens in processing water. Chlorine, as you know, is
19 the most commonly used antimicrobial in the produce
20 industry, but there are additional -- there are other
21 antimicrobial chemicals that are under research at this
22 time.

23 General guidelines for the use of the
24 antimicrobial in processing water are shown here. First
25 and foremost is to certainly follow any applicable FDA and

1 EPA requirements. Secondly, follow manufacturer's
2 **directions**. That would help ensure the safety and efficacy
3 **of** the use of that antimicrobial. And then, after using
4 **one**, follow up with a clean-water rinse.

5 It is important to remember that antimicrobial
6 **washes** may reduce, but not eliminate, pathogens on the
7 surface of produce and in water. Some typical reductions
8 may be from 10 to one hundredfold. As organic material,
9 such as plant material, dirt, and debris builds up in the
10 **water**, the effectiveness of antimicrobial chemicals will
11 decreased. GMPs will include a prewash to remove the bulk
12 of the field soil, and adding overflow water or changing
13 water is needed. Operators should also monitor chemical
14 levels, and add additional microbial as needed.

15 Are there any questions or comments on processing
16 water?

17 Yes. Could you go to the microphone, please.

18 ABRAHAM I. TENZER

19 BONAGRA

20 MR. TENZER: Are you aware of any tests that we
21 can use for **Cyclospora**?

22 MS. SALTSMAN: Excuse me. I didn't --

23 MR. TENZER: **Cyclospora**.

24 MS. SALTSMAN: Yes.

25 MR. TROXELL: Testing for **Cyclospora**.

1 MR. TENZER: I understand that they are still
2 Developing tests for **Cyclospora**, because the existing tests
3 **are** not reliable.

4 MR. TROXELL: That's my understanding, that the
5 analytical methods are under development, and it's very
6 difficult --

7 MR. TENZER: I spoke with Michael, and that's
8 where I got my information. So how could we try to
9 eliminate **Cyclospora** if we couldn't test for it?

10 MS. SALTSMAN : Well, we already have said many
11 times that we have a lot of gaps in our knowledge on this
12 area of the agricultural -- and a lot of the research going
13 on now is to answer and address those questions that you
14 have. I mean, that's a very --

15 MR. BALDWIN: The methodology that exists is not
16 perfect. What we're trying to do is to enhance the
17 recovery. Right now, we're getting about a 30-percent
18 recovery on the spores, and we can do some DNA testing, too.
19 So the capability is there. It's just that we're not
20 comfortable that we've gotten the kinds of recoveries that
21 we ought to have.

22 MS. SALTSMAN: All right. Animal manure or
23 **biosolids** can be a beneficial fertilizer and soil amendment,
24 but they also represent a significant potential source of
25 human pathogens. One in particular that you're heard about

1 **is** Escherichia **coli**, or E. **coli**, 0157:H7. It originates
2 primarily in the ruminants, such as **cattle**, sheep, and deer,
3 **which** shed it through their feces.

4 Those who use **biosolids** are no doubt aware of EPA
5 regulations that are already in place. Requirements for the
6 use of **biosolids** on non-public land, including land for
7 growing food crops, are set out in Title 40 of the Code of
8 Federal Regulations, Part 503. Part 503 requires either
9 elimination of the pathogens or significant reduction of
10 pathogens, along with certain restrictions.

11 One restriction is for the minimum times between
12 the application of **biosolids** and harvest of different foods
13 or feed crops. The minimum time interval may be as much as
14 26 months. Many states have additional restrictions, such
15 as limiting the type of crops that may be grown in fields
16 and orchards to which **biosolids** have been applied. So
17 operators need to be aware of their own states'
18 requirements, in addition to federal requirements.

19 The use of manure in the production of fresh
20 produce must be closely managed to limit the potential for
21 pathogen contamination. Good agricultural practices for
22 handling manure include treatments to reduce pathogen levels
23 and maximizing the time between manure application to crop
24 fields and harvest of those crops.

25 Growers should be alert to the presence of fecal

1 matter that may be introduced into the product growing and
2 **handling** environments. Potential sources of contamination
3 include use of untreated or improperly treated manure,
4 **nearby** manure storage or treatment areas, livestock, **dairy,**
5 **or** poultry operations, and high concentrations of wildlife.

6 The guide highlights some treatments to reduce
7 pathogens in manure. There are both passive and active
8 treatments. Passive treatments rely on time and the
9 environment, temperature and moisture fluctuations, and **UV**
10 irradiation. For passive treatments, manure should be well
11 aged and decomposed before being used. Active treatments
12 include pasteurization, heat drying, anaerobic or aerobic
13 digestion, alkali stabilization, or a combination of
14 treatments.

15 Composting is a controlled and monitored process
16 commonly used to reduce the microbial hazards of raw manure.
17 The high temperature generated during composting can kill
18 most pathogens in a number of days. Thus , the risk of
19 microbial contamination from composted manure is reduced
20 compared to untreated manure, but this is not a perfect
21 world, and composting is not a perfect process.

22 Some pathogens have a higher thermal threshold
23 than others, and may survive composting. The time and
24 temperature required to eliminate or reduce microbial
25 hazards in manure or other organic materials may vary

1 depending on the regional climate and the specific
2 management practices of an individual operation.

3 Some guidelines when handling or storing manure
4 are shown here. Growers should review existing practices
5 and conditions to identify situations where manure might
6 contaminate produce. Manure storage or treatment sites
7 close to fresh produce fields increase the risk of
8 contaminating the produce, the fields, and possibly water
9 sources.

10 Growers should follow good agricultural practices
11 such as securing manure in storage areas or establishing
12 runoff controls to minimize contamination of produce from
13 manure in open fields, compost piles or storage areas onto
14 nearby maturing crops. Rainfall onto manure piles may
15 result in **leachee** containing pathogens. Growers may want to
16 consider covering manure storage or treatment areas, such as
17 under a roof or appropriate covering.

18 Obviously, untreated manure carries a higher risk
19 of contamination compared to treated manure. Applying raw
20 manure to produce fields during the growing season by, say,
21 broadcasting or side-dressing, is not recommended.

22 Growers may reduce the risk of contamination from
23 manure by maximizing the time between application of manure
24 to a field and harvest. As mentioned this morning, the
25 National Organic Standard board, formed under the Organic

1 Food Production Act of 1990, recommends that raw manure not
2 be applied within 60 days of harvest of organic crops
3 intended for human consumption.

4 A problem or concern here is that no one knows for
5 sure how long pathogens can survive in the field or on
6 produce, or how pathogens' survival may be influenced by
7 environmental conditions.

8 Finally, treated manure. Composting and other
9 treatments may reduce, but might not eliminate, pathogens in
10 manure. It is unknown to what extent the pathogens will
11 survive treatment and may possibly regrow in treated manure
12 that is stored after use or before use. Therefore, to the
13 extent feasible, growers using treated manure may want to
14 consider some of the recommendations made for untreated
15 manure, such as maximizing the time between application and
16 harvest.

17 Now, this concludes the section on manure. If you
18 have any questions, I would be glad to take them now.

19 Yes.

20 PAT PASWATER

21 INTEGRATED WASTE MANAGEMENT BOARD

22 MR. PASWATER: I'm Pat Paswater with the
23 Integrated Waste Management Board, and I was curious on your
24 one statement here relative to composting that may vary
25 according to different regions as far as pathogenic kill and

1 **whatnot.** What do you predicate that on, if the temperature
2 is constant in pile, in North Dakota versus California? Is
3 it variance by region of what is considered an optimum **time-**
4 temperature kill in a different region?

5 MS. SALTSMAN: Well, the whole issue has been the
6 time-temperature variations throughout, and they don't have
7 enough data on it to really come out with specific
8 guidelines.

9 MR. PASWATER: Yes. There's the inference,
10 though, that the local climate influences the **time-**
11 temperature in the pile, if, like in the 503 regulations,
12 the stipulation is for a minimum time-temperature
13 relationship of a certain degree over a period of time, and
14 your statement here infers that that might not be a valid
15 approach.

16 MR. TROXELL: The issue is the time-temperature.
17 The question -- I mean, how many farmers are putting
18 temperature probes in the piles? And, you know, if you're
19 up in North Dakota, and the pile is frozen on the surface,
20 versus Florida, where it's still 75 degrees, there's quite a
21 difference in the time-temperature curve. That would be the
22 main issue.

23 MR. PASWATER: I would suggest a little
24 clarification of that point in the guidelines.

25 MR. TROXELL: Thank you. That's a good point.

1 MS. SALTSMAN: Yes. Thank you for that comment.

2 There is no slide up, so this is now the
3 sanitation and hygiene section, and I just want to preface
4 this by saying that we must recognize that we have a very
5 **diverse** agricultural work force in this country that is made
6 up of individuals with different backgrounds and cultures.
7 It cannot be assumed that this work force knows about or
8 practices good hygienic practices while working with fresh
9 produce. The guide, therefore, recommends that all
10 operators establish good hygienic practices that should be
11 practiced and followed by everyone who works with or handles
12 fresh produce.

13 Perhaps the first step in establishing a good
14 hygiene program begins with growers and packers being aware
15 of existing state and federal regulations regarding
16 standards for worker hygiene. For example, the Occupational
17 Safety and Health Act has standards for protecting worker
18 health in both the field and packing facilities. Now, OSHA
19 standards aim to protect workers. Coming from the viewpoint
20 of protecting the produce, we must remember that infected
21 employees will increase the risk of transmitting food-borne
22 illnesses. Therefore, all personnel should comply with
23 established hygienic practices.

24 What can employers do? We recommend that they
25 establish a training program to teach good hygienic

1 practices. Each program should be geared towards the level
2 of understanding of the workers. A formalized program,
3 along with periodic reevaluation and follow-up training, has
4 been proven to be effective in other segments of the food
5 industry. Operators or the person in charge of employees
6 should also become familiar with typical signs and symptoms
7 of infectious diseases.

8 Now, we had comments to our last version of the
9 guide saying that you can't expect operators to become
10 physicians, and we aren't asking for that. We are just
11 saying the Food Code, the FDA's Food Code, **gives typical**
12 signs and symptoms of infectious diseases that are used
13 throughout the food industry. By being aware of these signs
14 and symptoms, you might be able to question a worker whether
15 or not they might be ill, and that's just simply taking a
16 precaution that's a wise one.

17 We do recommend that workers with **diarrheal**
18 disease or other signs of infectious diseases not work with
19 fresh produce or produce-handling equipment. Lesions that
20 contain pus that are located on parts of the body that might
21 have contact with fresh produce can contaminate it, so
22 operators should provide some kind of protection for those
23 employees who might have a lesion. If a lesion cannot be
24 adequately covered to prevent it from making contact with
25 produce, the worker should not be working with the fresh

1 produce.

2 The guide also mentions the use of gloves, and we
3 received a number of comments questioning the recommendation
4 to use gloves as an alternate hygienic practice. However,
5 we had many comments that indicated that gloves are a common
6 practice among certain agricultural practices. Therefore,
7 we only recommend that gloves, if they are used as an
8 alternative practice, that they be used in combination with
9 good hand-washing practices, and it's very important to
10 insure that glove use is not -- or the use of gloves do not
11 become another vehicle for carrying pathogens and
12 contaminating produce.

13 As already mentioned, we encourage a training
14 program. This simply highlights some things we mentioned in
15 the guidance document about what to teach. We would
16 encourage that everyone be taught the importance of good
17 hygiene and what can happen in its absence. Teach them the
18 importance of good hand washing and hand-washing techniques.
19 Don't assume that everyone knows how to wash and dry their
20 hands. This simply task is an important one, and it ought
21 to be done correctly.

22 At our last group of public meetings back in
23 January or December, we had a comment from an employer who
24 said, "I've never thought about that, that my employees may
25 not wash their hands correctly," and he mentioned that he

1 may have to -- that maybe he needs to reevaluate that.

2 With respect to toilet facilities, the guide
3 recommends that workers be encouraged to use available
4 facilities to reduce the potential for cross-contaminating
5 **fields**, produce, other workers, and water supplies. Be sure
6 that workers are given the opportunity to use toilet
7 facilities when needed, and not simply when they are given
8 the time for a break.

9 Provision of toilet facilities for workers is
10 required by law. We **don't** repeat the law in the guidance
11 document, but we make reference to it. OSHA has two
12 separate laws under -- 29 Code of Federal Regulations 1928
13 applies to field sanitary practices, and for facility
14 sanitary practices, 29 Code of Federal Regulations 1910
15 applies to packinghouses or packing facilities. So those we
16 just want you to be aware of.

17 Some general practices to apply to sanitary
18 facilities, including toilets and hand-washing facilities,
19 are that they be accessible. They should be properly
20 located so as not to be near a water source used in
21 irrigation or in an area subject to potential runoff in the
22 event of heavy rains. Likewise, they should be well
23 supplied with paper, a water basin, water, **soap**, sanitary
24 hand-drying devices, and a waste container. All facilities
25 should be kept clean and sanitary, and containers used to

1 store water for hand washing should be cleaned and sanitized
2 on a routine basis and then refilled with potable water.

3 When handling sewage disposal, operators should
4 also consider following all applicable EPA regulations.
5 Under 40 CFR Part 503, we've mention of this already today.
6 They indicate proper disposal of sewage. Tank trucks should
7 have direct access to toilets when servicing them. For all
8 toilets, it's important to have a plan for containment of
9 effluent in the even of a spill or leakage.

10 We have seen one operation where toilet facilities
11 were moved in the field on a tractor bed as the workers were
12 harvesting the crops. This situation certainly maximized
13 the accessibility of the toilet facilities to the workers,
14 but care must be taken to ensure that the facilities do not
15 contaminate the field and produce. In this particular
16 instance, they did not, because they were following along in
17 parts of the field that were already harvested.

18 Now, before continuing on with field sanitation, I
19 would welcome your questions or comments on the worker
20 health **section**.

21 (No response.)

22 MS. SALTSMAN: Some good manufacturing practices
23 that are recommended when working in the field are shown
24 here. Most of these are pretty much just good common sense
25 and good practice. One, just cleaning harvest storage

1 **facilities** prior to use, repair or discarding damaged
2 **cartons**. When you can't clean a carton properly, it's going
3 **to** -- there's a tremendous potential for it to hang on to
4 **pathogens** that may be in the mud and dirt that they come in
5 **contact** with. Then clean muddy containers before use.
6 **Remove** as much dirt and mud from the produce as practicable
7 **in** the field. Leave it where it came from. And, lastly,
8 **insure** produce that is packaged in the field is not
9 **contaminated** in the process.

10 It is also important that field equipment be used
11 appropriately, where it is during planting, growing, or
12 harvesting season. Field equipment includes a wide variety
13 **of** things, not just the large machinery that you commonly
14 see, but it includes cartons, baskets, tables, cutting
15 materials, packaging, buckets, aprons, anything.

16 For the large equipment, if any equipment has been
17 used to haul garbage or manure or other such material, it
18 should not be used with fresh produce, unless that piece of
19 equipment has been cleaned and disinfected first. The guide
20 recommends that operators assign someone to be in charge of
21 equipment and be responsible for ensuring that it is
22 maintained, working properly, and as clean as practicable.

23 For all packing facilities or packinghouses and
24 the grounds around them, a general recommendation is that
25 they be maintained in good condition so as to reduce the

1 potential for microbial contamination of fresh produce.
2 This would focus on keeping grasses cut, debris, trash, old
3 equipment hauled away. Anything that could harbor or fester
4 pests should be cleaned up and kept away from the packing
5 facility.

6 Similar guidelines here as to the field is to
7 remove as much dirt and mud as practicable from produce
8 outside the packing facility or packing areas. Repair or
9 discard damaged cartons, and then clean muddy pallets,
10 containers, and so forth before using to transport fresh
11 **produce.**

12 In one our site visits, we saw a carrot packing
13 facility where trucks seemed to be unloading as much dirt as
14 they were carrots. This extra field soil certainly placed a
15 tremendous burden on the cleaning operations in that
16 facility.

17 Packing and packaging equipment, like field
18 equipment, needs to be kept in good working condition, as
19 clean as practicable, and used appropriately to prevent
20 microbial contamination of fresh produce. All packing areas
21 should be cleaned at the end of each day of use, or more
22 frequently as needed.

23 Packing facilities that are not enclosed certainly
24 come with their own sets of concerns with respect to
25 contamination, and blowing air can easily carry contaminants

1 onto the produce. So that requires much more caution, when
2 you're going to be packing out in the field.

3 Operators should ensure that cooling systems are
4 maintained in proper working order and be kept clean. It is
5 also important to clean all product storage areas on a
6 regular basis, removing dirt, debris, and produce waste.

7 Finally, for all packing facilities, we are
8 recommending that you establish a pest control system. The
9 guide recommends that operators establish a pest control
10 system, maintain the grounds in good condition, monitor and
11 maintain facilities regularly, try to block access of pests
12 into the enclosed facilities, and to use a pest control log
13 which could be used to monitor or to register when
14 treatments have been used, were they successful, follow-up
15 inspections, and so forth.

16 Now, before going to the last section of the
17 guide, I'd like to hear any comments you might have on field
18 and facility sanitation.

19 (No response.)

20 MS. SALTSMAN: A new section that appears in this
21 guide that did not appear in the last one was put in in
22 response to comments. Operators who permit customers to
23 pick their own produce or who sell produce directly to
24 customers should use the opportunity to teach customers
25 about good handling practices for fresh produce and to

1 promote good hygienic practices.

2 Customers should follow established hygienic
3 practices, just as you would require employees to do. The
4 guide recommends that all customers who pick produce be
5 provided with properly equipped hand-washing stations in the
6 field, and that there be clean, well equipped, and
7 convenient restrooms for their use. Finally, we encourage
8 operators to educate consumers about washing produce before
9 eating produce raw.

10 Transportation, another important area. Again,
11 throughout the whole guidance document, we have maintained a
12 general statement that anything that comes in contact with
13 fresh produce has the potential of contaminating it, whether
14 it's water, manure, workers, and certainly the
15 transportation segment is no exception.

16 Produce may become contaminated during loading,
17 unloading, storage, or transport operations. Workers
18 involved in the transportation field should follow the same
19 kind of good hygienic practices that are required for field
20 and facility workers.

21 The guide recommends that operators ensure that
22 someone is responsible for inspecting trucks and transport
23 cartons before loading produce. Inspect for cleanliness,
24 odor, and any signs of contamination. Find out what prior
25 loads were carried in the vehicle before loading the

1 vehicle. It may be prudent to clean and disinfect it before
2 loading fresh produce.

3 We had one comment from an operator who
4 automatically makes it his business to clean transport --
5 clean trucks and any cartons before loading his produce,
6 just because he doesn't want to have to try to guess what
7 the transport carton was used for.

8 So it's important to keep transportation vehicles
9 clean in order to reduce microbial contamination or **CROSS-**
10 contamination of fresh produce. The bottom line, again, is
11 to try to focus on prevention of problems instead of trying
12 to put out the fires once they begin.

13 During transportation, it is recommended that
14 proper storage temperatures be maintained to ensure both the
15 quality and the safety of fresh produce. Load trucks or
16 transport cartons in a manner in which you minimize damage
17 to fresh produce.

18 Trace-back. You've heard that mentioned earlier
19 today. Trace-back is the ability to track food items from
20 the consumer to the source of the products. Effective
21 trace-back programs can serve as an important complement to
22 good agricultural and manufacturing practices intended to
23 prevent the occurrence of food safety problems.

24 This just gives an overview of a trace-back
25 process that we present in the guidance document. It begins

1 with identifying the suspected food item and the point of
2 service, where the food that caused the outbreak was served
3 or sold. Next, pertinent product information is gathered,
4 such as identifying product type, packaging, labeling, lot
5 numbers, expected shelf life, and so forth.

6 Identifications and documentation of the source of
7 the suspect shipments of the produce can be obtained up to
8 the point of service in one of two ways, one, by tracing lot
9 numbers, or by reviewing delivery records for information
10 about the time period when the product was saleable and
11 **useable**, combined with employee interviews at all points in
12 the distribution chain.

13 Now, this option requires a lot of time and
14 effort, and the information gained may be less than perfect.
15 There is absolutely nothing easy about trace-back when
16 you're dealing with produce, and it's very difficult, and
17 there are no clear answers on the best way for it to be done
18 at this point, but the guidance document just recommends
19 that operators do what they can to cover their own
20 responsibility in the process.

21 Some of the challenges for the fresh produce are
22 shown here. Applying a trace-back system does have many
23 challenges, and one of which is that fresh produce has a
24 short shelf life, and is often gone by the time an outbreak
25 is reported. Current practices in fresh produce marketing

1 and distribution systems makes a direct identification of
2 the source difficult.

3 Two such practices are the use of recycled
4 shipping crates and commingling of produce during
5 distribution or at retail. Further, if an implicated
6 location such as a field or packing facility is identified,
7 the source of contamination may no longer be present when
8 investigators arrive at the scene.

9 In spite of the challenges, an effective traCe-
10 back system offers several benefits. First of all, it may
11 lead to a specific region or packinghouse or field, rather
12 than to an entire commodity. It may limit the population at
13 risk. It might help minimize unnecessary expenditure of
14 already scarce public health resources.

15 Probably, from the operator's point of view, very
16 important is to help reduce consumer anxiety about eating
17 the produce. We are never trying to minimize the importance
18 of eating fresh produce, and are certainly going to
19 encourage that more fresh fruits and vegetables be consumed.
20 Improved trace-back may also lead to information about the
21 sources of contamination that might help refine future good
22 agricultural and manufacturing practice recommendations for
23 minimizing contamination.

24 Now , once good practices are in place, it's
25 important to ensure that the process is working correctly.

1 We encourage the regular monitoring of the operations to
2 ensure that all practices are being followed. Without
3 accountability, the best attempts to minimize risk of
4 contaminating fresh produce are going to be subject to
5 failure.

6 Now, this concludes my presentation on the
7 guidance document. Are there any questions on any section
8 that you would like to raise?

9 DONNA M. GARREN

10 **BOSKOVICH FARMS, INC.**

11 MS. GARREN: Donna Garren from Boskovich Farm.
12 You made mention to the transportation industry. Being that
13 we are growers and packers and processors, our missing link
14 tends to be the transportation industry. When trucks come
15 in, a lot of them are independent trucking agencies, and
16 between retail and end, they're our only links, and if
17 they're not clean, or if they don't have certain standards
18 that they need to abide by, how are we going to monitor? I
19 know you've mentioned something about training or
20 educational programs for the trucking industry. Is that in
21 the works, or what agencies are going to be responsible for
22 that?

23 MR. TROXELL: Let me make a couple comments on
24 that issue. It's been a while ago now, so I don't remember
25 exactly when we put out a Federal Register advanced notice

1 of proposed rule making dealing with transportation issues.
2 We have not moved to do a proposal, but, in the meantime,
3 the trucking industry has taken a great deal of interest in
4 doing industry guidance, and they're actively pursuing
5 developing industry guidance.

6 What's interesting is that the trucking industry
7 seems to have pieces of guidance. You know, one group has
8 some, another group has some, but this effort now which
9 we're doing in partnership with Food Safety Inspection
10 Service of USDA is going to bring all the groups together,
11 and they can, you know, build on each other's work already
12 done. So they're well aware of our concerns, and we're
13 pursuing those.

14 MS. SALTSMAN: Yes, sir.

15 MR. TENZER: Abe Tenzer, Bonagra. I would like to
16 comment about two or three points. The first point is that,
17 in the sanitation section, mention was made that organic
18 matter may affect the efficacy of chlorine in leaving enough
19 chlorine to sanitize the fruits and the vegetables, and your
20 recommendation is to add more chlorine, and I would like to
21 address the subject later from a scientific point of view.

22 Having chlorine doesn't necessarily mean that you
23 will get better sanitation. There is a certain compound
24 that you need which, is hydrochloric acid, to kill the
25 microorganisms, and if you don't monitor the HOCL, you don't

1 know what's going on in your sanitation wash to begin with.

2 Second thing is, you could not rely on people
3 coming in every half-an-hour or 20 minutes or 15 minutes and
4 adding chlorine, because you don't know what the temperature
5 conditions were, and the conditions for the formation of
6 hydrochloric acid are very, very limited, both in PH and
7 temperature range, so that, if you don't have an automatic
8 system that monitors and injects, and ascertains that the
9 HOCL level is steady, you don't have a steady sanitation.
10 To this effect, our company and some other companies have
11 developed monitoring systems, and I would like to address
12 this issue later on, if I may.

13 Coming back to the comments about the practices,
14 the field practices, one of the biggest problems that we
15 found out with our growers both in America and in Mexico is
16 that they are using the same things. They started by using
17 wooden bins, which are, A, a big no-no in this industry and
18 shouldn't be used at all. They switched to plastic, big
19 bins that are coming in from the fields loaded with the
20 tomatoes, the peppers, and things like that.

21 Those bins have to be sanitized before they go
22 back to the fields, because, if there is any contamination
23 in any of the bins, it will cross-contaminate the new
24 produce that is going to be shipped the second time around,
25 or the third time around, or the fourth time around, and I

1 don't believe that the guidelines have specifically
2 addressed this issue.

3 Another thing which I would like to add is in the
4 area of transportation. You mentioned that one of your
5 comments indicated that he sanitizes every truck that comes
6 in, and I think that that should become mandatory. We know
7 only of one or two large trucking companies that are forcing
8 their drivers to sanitize by using sanitation chemicals and
9 high-pressure hoses, with water and desanitizer, the trucks.
10 Our company has developed a sanitation product for trucks,
11 and so do other companies. The technology is available, and
12 we should incorporate it into the guidelines.

13 **That's** basically what I would like to comment in
14 the various sections, and I hope I didn't take too much of
15 your time, but I know that each one of the comments has
16 proven to be very critical to us.

17 MR. TROXELL: Thank you.

18 MS. SALTSMAN: Thank you for your comments.

19 LEE FRANKEL

20 FRESH PRODUCE ASSOCIATION OF THE AMERICAS

21 MR. FRANKEL: My name is Lee Frankel. I'm with
22 the Fresh Produce Association of the Americas, and I have
23 just some specific comments, more on how certain items are
24 presented in the guidance document, and wanted to give a
25 little feedback.

1 I guess one question that would help maybe clarify
2 from the nontechnical user's point of view, there's a
3 definition of "sanitized" being a five-log reduction in the
4 microbial count, and I guess just a general question is,
5 well, what's the starting point? Is this like a dirty
6 vehicle, contaminated implement that we're hosing off, or is
7 this something that we generally keep clean that we need to
8 make practically sterile, and maybe just a little bit more
9 explanation there would be helpful.

10 I guess another comment was on section two, on the
11 **water**. I guess that's subsection 2.1. It talks about a
12 general consideration for water used in a series of
13 processes, and it makes a statement that maybe the water in
14 the first dump tank doesn't need to be as clean as the last
15 water.

16 I was thinking maybe we should take that statement
17 or implication out, if, you know, we're talking about
18 something like tomatoes, later on, that says, you know, if
19 there's a difference in the pulp temperature compared to the
20 first wash water temperature, that there will be
21 infiltration of water in that first stage, and maybe that's
22 the area where it's the most critical to have the cleanest
23 water.

24 I guess in the same section on water, I guess 2.2,
25 in the wash water, specifically, it says, "Use appropriate

1 wash methods," and then it sort of mentions maybe using hot
2 water surfactants, and I guess we're making the
3 recommendation just to go ahead and have, right there, a
4 little bit more explanation as to why that's useful from a
5 producer's point of view.

6 I guess one of the other bullet points was
7 consider the use of sanitizers, and it talks about
8 monitoring chlorine levels. Maybe we could make it
9 sanitizer-neutral, and talk about sanitizing agent levels
10 instead of chlorine levels.

11 Let's see. Then I guess it talks about
12 considering the wash water temperature, and I understand you
13 got complaints from certain people that **pre-cool** product,
14 and you switched back to emphasizing on tomatoes again, and
15 I guess my understanding is it's not so much maybe tomatoes
16 in particular, but anything that has a stem-end scar or a
17 harvest scar. That's where the opportunity -- where you're
18 getting this pressure differentials, and maybe if we can
19 avoid being so specific on tomatoes, and that's useful about
20 harvest scars, to make that more explicit.

21 Let's see. I guess, on section four, sanitation
22 hygiene, there's references to damaged cartons. I guess
23 **"cartons"** sort of has a specific connotation of kind of a
24 final carton that the product is shipped in to the market,
25 as opposed to how much if you're looking -- maybe the word

1 "container" would be better if we're talking about harvest
2 containers as well as shipping cartons, or just all the
3 different areas, and maybe "containers" has less industry
4 connotation and would be all-encompassing.

5 Let's see. I guess those were -- well, I guess
6 one other one was --

7 UNIDENTIFIED SPEAKER: Excuse me, Mr. **Frankel**.
8 Would you speak up? We can't hear you in the back.

9 MR. FRANKEL: Okay. I'll speak closer to the
10 mike, and I'm just about finished, anyway, so I apologize.

11 The 'other one was talking about removing dirt, and
12 in the guidance document itself it focuses solely on the
13 fact that dirt may contain fecal contamination, but I guess
14 some scientists are talking about the high-level microbial
15 activity in just any soil, anywhere, and I don't know if
16 that's a threat to human health that we need to be worried
17 about, or maybe just clearing up one way or the other, I
18 guess, might be helpful as well. Thanks.

19 MS. SALTSMAN: Thank you for those comments.

20 We will be getting copies from the transcripts
21 here, so your comments will be considered. I'm not writing
22 them down. That's why I **don't** have to. Somebody else is
23 doing that.

24 MR. TROXELL: Other questions?

25 (No response.)

1 MR. TROXELL: If not, I have a question. There
2 has been -- obviously, one of the hot spots in this has been
3 **wild** game, wild animals, and there's been concern about how
4 the wording has been cast about the balance between
5 protecting, you know, the wildlife, versus the potential for
6 contamination. So what I would like from the audience,
7 either now or in writing, is, you know, wording for dancing
8 through that that will help us cast it in a way that is more
9 appropriate. I mean, we really need help on these kinds of
10 things, so we can strike the right balance.

11 MODERATOR VIOR: Are there any other questions
12 specific to what was presented just now in regards to the
13 presentation? Step up.

14 MR. TENZER: Are there any other sanitizers
15 approved to this moment in time? It's directed to you, Ted.
16 Any other sanitation systems, methods, chemicals approved to
17 this point in time to replace the conventional sodium
18 hydrochloride or chlorine dioxide, such as **W** or ozone?
19 What's the status on that? **That's** question number one.

20 Question number two, what are we going to do about
21 determining the maximum allowed microbial contamination on
22 the various commodities, in numbers of colonies per gram or
23 any other description? What are we doing about that, and,
24 particularly, are we going to abide or be guided by
25 guidelines that have been developed in Canada, in the United

1 kingdom, and in Australia, in Israel, in **general practice,**
2 **about** this minimum requirement? Because it's very, very
3 **difficult** to work without having a -- number to hang our
4 Laboratory coat on, so to speak. Thank you.

5 MR. TROXELL: On the second question, let me say,
6 **if** you have some information to shed some light on that,
7 **along** with the scientific basis to support the numbers, we
8 **would** be glad to consider it. We're focused on pathogens,
9 **and** any other endpoints we would look at would be used as
10 **surrogate** markers, in lieu of being able to detect the
11 **pathogens,** but we'd have to be able to -- we'd want to,
12 presumably, be able to link that surrogate to the likelihood
13 **of** a pathogen being present.

14 I cannot, unfortunately, provide, you know, song
15 and verse on each of the disinfectants. I know ozone is
16 used in some drinking water systems as a disinfectant,
17 sometimes in combinations with chlorine or in lieu of
18 chlorine. So, you know, we just need to use these in
19 accordance with the federal regulations. It's either food
20 additive regulations or EPA's regulations on disinfectants
21 for use on raw agricultural products.

22 We realize there's a great need to clear more of
23 these, to provide flexibility in doing these various
24 sanitizing operations, and that's something that both
25 agencies need to work **on, but,** in the **meantime,** there **is** a

1 packing facilities that kill reduction of microbial
2 contamination, like chlorination systems that we are
3 talking about, but in processing facilities, the -- of the
4 fresh vegetables, we are doing **HACCP** programs for that, and
5 it's mainly close to what we are doing there.

6 So my concern is where we are going to get exactly
7 what we are going to use in packing facilities. It will be
8 good manufacturing practices only, or we are introducing the
9 **HACCP** programs for that particular areas? Because **there's**
10 still a big debate there.

11 MR. TROXELL: If you would like me to comment on
12 that, I can take a minute. I mean, basically, HACCP
13 programs have basic sanitation operating, basic SOP,
14 sanitation SOPs, along with that program. So, if **you're**
15 able to accomplish a HACCP program or **HACCP-type** program,
16 whatever it meets, which incorporates sanitation SOPs, then
17 basically you will have achieved what we're trying to
18 achieve here, and probably more. So that's great.

19 MR. MUNIZ: Yes. I'm going with the HACCP
20 program, but it's still a big debate out there. People want
21 to use -- with a good manufacturing practices, in kind of a
22 quality control manner, instead of trying to set up a
23 critical control point there in the packing facility, when
24 the operation is similar, where we have in processing
25 facilities, in terms of using a chlorination system to

1 reduce the allowed of (sic.) bacteria. So that was only
2 my --

3 MS. SALTSMAN: Thank you.

4 Mr. **Frankel**.

5 MR. FRANKEL: Good afternoon, again. My name is
6 Lee **Frankel**, and I'm speaking on behalf of the Fresh Produce
7 Association, which is a -- the core members are importers
8 who import approximately 4,000,000,000 pounds of fresh
9 produce from Mexico each year, and I guess, given that I've
10 already made some specific document comments, I'm going to
11 have make some general Food Safety Initiative comments.

12 The first request is that the FDA, and USDA in
13 particular, should try to help more clearly outline the
14 goals of risk reduction that we're hoping to achieve, beyond
15 just a general statement of safer food. I think virtually
16 all within the industry and consumer groups alike support
17 safer foods, but without, maybe, some specific goals in
18 mind, it makes the task to try to motivate the millions of
19 people around the world involved in the production processes
20 properly motivated (sic.).

21 Then I also wanted to kind of call your attention
22 to, I guess, a 1998 article from the Columbia Journalism
23 Review that sort of went back and tried to find out where
24 does this 9,000 deaths annually number come from, and I
25 guess they -- you know, it wasn't USDA or it wasn't **CDC**, but

1 it was back to the original papers done by a couple
2 professors for their mathematical models, and how it's not
3 necessarily a real kind of peer review type of number.

4 That's sort of just like as an example, that if we
5 can, you know, also encourage kind of a devotion of
6 resources to establishing some types of more accurate risk
7 analysis that growers and producers and shippers can use to
8 help guide them prioritize what should be the first things
9 that we're attacking, or what's the most important things
10 that we can be doing in order to achieve a safer food
11 supply .

12 The second general request is that the guidance
13 document should maybe more clearly reference the entire
14 farm-to-table pathway, given the kind of big title from the
15 guide, "Guide To Minimize Microbial Food Safety Hazards for
16 Fresh Fruits and Vegetables." You know, I guess, again, you
17 know, maybe an area just to show or make the industry feel
18 like you're not picking on us, you're taking care of the
19 whole subject, is maybe reference some of the work you've
20 already done with the 1997 Food Code as it relates to
21 restaurants, and what you're doing on that aspect.

22 I guess, in addition, I'll forward this on to you,
23 but there is a 1998 survey by Audits International which
24 surveyed -- 99-percent of the U.S. household kitchens that
25 they surveyed were "unacceptable," sort of based on some of

1 these Food Code recommendations and guidelines, and sort of
2 in short, just as, you know, our association recommends that
3 we kind of reemphasize the need for strong educational
4 efforts, and maybe even guidelines, maybe even in this
5 document itself, that the home consumer can use to
6 participate in the process.

7 One of the other points is just a request, again,
8 that the administration effort for food safety continue to
9 respect the concept of national treatment on this issue. We
1a believe that food should be held to the same level of safety
11 regardless of the country of origin.

12 I guess recently I spoke with the staff member for
13 one of the congresswomen that introduced some of the FDA
14 expansion, or encouraging them to do more foreign
15 inspections, and giving them the authority, and changing the
16 definition of "adulterated food," and the comment from that
17 staffer was, 'Well, we don't care. Imports have to be 10
18 times safer than what we require of U.S. producers. You
19 know, **we're** just interested in safe foods."

20 I think, you know, if we kind of even lose that
21 veneer, that this is about a public health issue instead of
22 a trade issue, that -- you know, I guess more work needs to
23 be done on that, and I guess one request is -- I know both
24 the FDA and the USDA have legislative affairs offices, and
25 maybe if there can be some increased activity to try and

1 educate the people that will be passing the laws and the
2 regulations, I guess that would be greatly appreciated.

3 I guess one of the other points along that front,
4 as I looked back and looked at the sort of food-borne
5 illnesses associated with produce reported since 1990, and
6 saw that the incidence were roughly proportional with the
7 market penetration of imports and domestic foods -- I guess,
8 again, if that could maybe be reemphasized to some of the
9 policy makers, that just if we ban all imports and replace
10 that with domestic production, that the food-borne illness
11 incidence will probably not be changed in any measurable
12 way.

13 I guess I would like to give a brief summary of
14 some of the major programs some of the different growing
15 regions in Mexico have undertaken on this effort. I guess
16 you'll be hearing somebody from the state of **Sinaloa**, and
17 their growers' association has developed guidance document
18 for their growers. They've done a baseline survey of their
19 hundred largest produce farms, and they have a dedicated
20 staff members to work individually with the growers to
21 correct some of the things they found during that baseline
22 survey, and, in addition, they've created a worker
23 sanitation training video.

24 The growers in the San Guetin region of Baja
25 California likewise have a dedicated staff, just on just

1 field sanitation, a hygiene education program, I guess some
2 **GAPs** and good manufacturing practices for their main
3 commodities, and the state of Sonora has authorized funding
4 for 40 full-time staff members to go throughout the entire
5 state and conduct that type of work.

6 I guess the reason I bring those programs out is
7 to show that, you know, there is a need for a concept of
8 regionalization like the USDA and FDA do with phytosanitary
9 issues and chemical residue inspections. You know, the U.S.
10 government recognizes that particular regions may be cleaner
11 than others, as well as individual growers, and I guess our
12 feeling is, if those growers or regions meet or exceed all
13 u.s. regulations, rather than relying solely on what a
14 foreign country's national policy is, that if we can show
15 we're producing safe food, that that should continue to have
16 access to the U.S. market.

17 So I would just like to reiterate that we support,
18 you know, the goals of the administration on this project,
19 and I wanted to say thank you for the changes that you did
20 make from the first draft to the draft you have now, and,
21 hopefully, with the upcoming memorandum of understanding
22 between the U.S. and Mexico, that not only will that sort of
23 help pave the way for us in foreign field visits, but also
24 closer coordination of the policy between the two countries.
25 Thanks again.

1 MS. SALTSMAN: Thank you.

2 Lorena. Ricardo, I think we might need your
3 assistance.

4 LORENA SANTANA

5 CADIS

6 MS. SANTANA: Good afternoon. My name is Lorena
7 **Santana**, and I represent CADIS, from **Culiacan, Sinaloa**, and
8 I will start to speak Spanish, and answer, and I'm sorry
9 because I can't do it in English.

10 I would like to comment on what my group has been
11 doing with the voluntary guidelines. We started by doing
12 a -- or diagnosing our hygiene and our cleanliness. It is a
13 sanitation --

14 MR. GOMEZ : Well, yes.

15 MS. SALTSMAN: Regarding -- sanitation practices?

16 MR. GOMEZ : Yes, yes.

17 MS. SANTANA: Okay. We visited some packinghouses
18 and fields, and we had some interesting results and
19 observations, which led us to make some conclusions, and
20 they started working on those.

21 During this evaluation, we found three things that
22 were very important that we consider, and they were
23 involvement, investment, and training of people. We were
24 then able to **catalogue** or classify the producers and packers
25 into three categories, and we found that some producers were

1 very much involved and very much up to date, and wanted to
2 be involved in following good practices, but we still have a
3 long way to go with some of the others that are not as up to
4 speed as these were.

5 We have a quality program, or program on **quality**,
6 and we have three different aspects of it, qualities of
7 physical qualities, chemical qualities, and microbial
8 quality, and the third one, of course, is the good
9 agricultural practices and good GMPs.

10 We found out that the most needed part was
11 education, and we have then developed a video for training,
12 and it refers to the good ag practices and good GMPs for the
13 workers both at the field and packinghouse.

14 We've also started to develop a program based on
15 standard operating procedures following the guide, and in
16 these SOPs, we're considering management, disposal, potable
17 water for the employees, and very many others. The list is
18 very long.

19 We are working very hard. I don't know whether
20 we've done a little or a lot, but we are working hard at it.
21 Thank you.

22 MS. SALTSMAN: Thank you, and thank you, Ricardo.

23 We have one more person, Mr. Tenzer.

24 MR. TENZER: For some reason, the overhead
25 transparency equipment was given back or is not here

1 anymore.

2 MS. SALTSMAN: No.

3 MR. TENZER: And if you remember, I mentioned that
4 I would maybe provide presentation. I don't know why this
5 happened. But since we don't have it, there's very little I
6 can do about it, so I'll have to talk instead of showing you
7 **what** we have done, and I would like to say a few things.

8 UNIDENTIFIED SPEAKER: Well, clearly, please
9 submit the entire -- all the materials, you know, in a
10 comment later. We'll include it in the record.

11 MR. TENZER: Fine. That's very kind of you. I
12 appreciate it.

13 First of all, there's a question of the five-log
14 production that I believe Lee Frankel mentioned, and the
15 juice people have gotten -- the **11th** Commandment, and the
16 question that I'm asked by the juice people, as we are
17 involved in the sanitation and microbial testing, is "What's
18 the minimum number that we can afford?" Because log five of
19 100,000,000 colonies is a different number than a log five
20 of 100,000 colonies. What's the meaning of the FDA
21 requirements of five-log reduction, for any number under any
22 condition?

23 Secondly, what's the contact time? Because
24 sanitation, as you all know, doesn't depend only on the
25 antimicrobial agent that we have. It depends on the amount

1 of time that we are really using the antimicrobial agent on
2 the fruits and the vegetables.

3 So I would like to call your attention to this
4 point. You have to be more specific. You couldn't just
5 state the general idea of five-log reduction, which is not
6 possible with chlorine unless you go to 1,000, 2,000, or
7 3,000 ppm, and even in alfalfa sprouts, doesn't -- kill the
8 Salmonella that you have in there.

9 so we are really in a limbo here, and by not being
10 specific, we are aggravating the situation, and I'm sure
11 **it's** -- bearing in mind that we have -- in the FDA and the
12 USDA, and in the industry in America, we can come up with
13 some more meaningful information. That's number one.

14 Now, the other thing is, there is only one
15 specification, to the best of my knowledge, that is
16 applicable to the sanitation to the fruits and vegetables,
17 and that's CFR 21 173.315. Am I right in that or wrong on
18 that? CFR 21 173.315 is the only specification that
19 specifies the antimicrobial agents that we are allowed to
20 use in washing and cleaning fruits and vegetables.

21 MR. TROXELL: There may be a few other references.
22 Some of those may already be listed on the graphs list or
23 something. So we'd have to --

24 MR. TENZER: Yes. Well, if something is listed on
25 graphs, you can just use it without making reference to this

1 particular specification?

2 MR. TROXELL: I'd have to get back to you on that.

3 MR. TENZER: Okay.

4 MR. TROXELL: I'm not exactly sure.

5 MR. TENZER: Okay. Right. And our company,
6 **Bonagra**, has developed a chlorine potentiator. It took US
7 about eight years and two-and-a-half million dollars to
8 develop it, and what we have done is we have applied
9 components that are specified in CFR 21 173.315, which is
10 the same specification that allows us to use chlorine, so
11 that it's considered to be a processing aid, and that
12 technology has been available in the United States for the
13 past eight years.

14 As you mentioned before, Ted, we need compliance
15 with the FDA or the -- you know -- specification. This, our
16 **CP**, the chlorine potentiator, is in full compliance with CFR
17 21, and was tested for simplicity by Gibraltar Testing Labs
18 way back in 1990, and was found to be nontoxic in '98, and
19 based on EPA -- so this technology is available, and it's an
20 American technology, developed in America, being used by
21 American companies, and we would like very, very much to
22 recommend that you include it in your guidelines. That's
23 number one.

24 Number two, the chlorine potentiator technology
25 allows us to work in packaging houses -- Up to a range of

1 100 degrees Fahrenheit, which you could not work with
2 regular chlorine, because, as you know, chlorine starts
3 evaporating at 55 degrees Fahrenheit, and conditions in most
4 of the packinghouses, both in America and Mexico and other
5 countries, are far from being 55 degrees. Only the
6 processing plants which are contained in buildings could
7 maintain this temperature range. So I would like you to
8 note that if you have a packinghouse, and you want to get
9 good sanitation, you may as well know about our technology,
10 and use it, if you can.

11 The third point is that the PH range that we are
12 usually working to obtain the hydrochloric acid, HOCL, is
13 usually between 6.5 to 7.5. In our particular testing, for
14 the past six, seven years, we found out that we can extend
15 the range of the HOCL formation up to between a PH of six to
16 a PH of 10.

17 The sum total of the system is, is that we have a
18 system which is much more effective in utilizing chlorine.
19 We can cut down on the amount of chlorine that we use, which
20 everybody would like to do, by 30 to 50-percent, and get a
21 much better -- by utilizing our technology with the
22 chlorine, and the result is that you get a cleaner produce
23 that has much less count of plant pathogens and human
24 pathogens in it.

25 We have demonstrated by studies that we ran with

1 Dairy Food Laboratories that this technology could eliminate
2 E. coli 0157:87 to the extent of five, six logs, under
3 certain conditions. This is why I asked the first question
4 to begin with, because, again, we are working against an
5 unknown requirement by the FDA, and we would like to clear
6 this up. Thank you very much.

7 JASPER E. HEMPEL

8 WESTERN GROWERS ASSOCIATION

9 MR. HEMPEL: I didn't sign in, but hopefully I
10 can --

11 MS. SALTSMAN: No problem. Good morning.

12 MR. HEMPEL: Thank you very much. I'm Jasper
13 Hempel. I represent the Western Growers Association, and on
14 behalf of Western Growers Association, I want to compliment
15 you for making the changes. This is truly -- one time in
16 our earlier grassroots hearing you heard us. You
17 accommodated most of the changes. I won't belabor the issue
18 of wild animals. That's an issue that we are going to be
19 commenting to you specifically on in our written comments,
20 and we'll try to provide some guidance in terms of written
21 language. But thank you. You've taken a big step forward.

22 Having said that, I don't want to be redundant,
23 but I do want to reiterate a couple of points that Lee
24 Frankel and others have made, and the question is, with all
25 due respect, it's not the question of "Why produce, why

1 now," but why are we focusing on the grower side of the
2 equation, harvest to transportation, as opposed to focusing
3 on where the real problem is, which is post-purchase food
4 handling practices?

5 I was delighted to hear that you are looking at
6 educating consumers, and we applaud that, and suggest that
7 you take the bulk of the resources that are available to you
8 and make that your primary focus, especially if your own
9 statistics and CDC's statistics confirm that over 70-percent
10 of food-borne outbreaks occur by post-purchase food handling
11 practices by unknowing consumers.

12 Having said that, again, though, we developed our
13 food safety guidelines because we believe that it's the
14 right thing to do, not only for our members but for
15 consumers, and for anybody that eats fresh fruits and
16 vegetables. They need to have assurance that we in the farm
17 community are doing everything we can to minimize microbial
18 contamination. Your guidance document furthers our goals,
19 as well.

20 So I wanted to share with you some of the things
21 that we'll be doing in the near future. You've already
22 heard of some of them, but what we would like to do at our
23 next iteration of our voluntary food safety guidelines is to
24 incorporate some of the concepts which you have presented in
25 your guidance document that we don't have in our guidance

1 document.

2 At the same time, we are working in cooperation
3 with the state of California and our friends in the grocer
4 community, California Grocers Association, to try to develop
5 a comprehensive trace-back system. Right now, we have
6 various forms of trace-back from the field to the first
7 point of distribution, whether that's supermarket, retail --
8 excuse me -- distribution, retailers, and food service.

9 We need to get beyond that point because now, if a
10 consumer gets sick, you can probably get it back as far as
11 the supermarket, but you can't, in many cases, get it back
12 to the field, and we agree with everything that has been
13 said so far of the damage to the industry as a whole if we
14 don't have a very specific trace-back system. So we are
15 working aggressively on that.

16 We're also working aggressively to develop an
17 educational program, and as many of you from government
18 know, Western Growers, along with United and other
19 organizations, have been involved with your educational
20 outreach efforts. Again, I say this with a certain amount
21 of respect. That is, we don't think you're going quickly
22 enough on education, and so we feel compelled to move a
23 little faster than you are.

24 To that end, we are going to build on the work
25 that the California Strawberry Commission has put together,

1 an outstanding quality assurance plan, and they have **allowed**
2 us to use that as a template for a textbook around which
3 we'll build a food safety curriculum, using university
4 scientists as well as public health and public food and **ag**
5 officials, and we plan to have our first educational guinea
6 pig seminar right around the first of September. What we
7 intend to do is to give some evidence of completion of this
8 program. We won't call it a certification, but it will be
9 some evidence.

10 Again, we appreciate all your efforts. I guess in
11 some ways it's giving us impetus to move quicker than you.
12 We want to stay ahead of you, if we can. But thank you for
13 coming to California. Thank you for sharing your views
14 today. Thank you.

15 MS. SALTSMAN: Thank you.

16 MR. TROXELL: Thank you, and we'll certainly use
17 as much of your work as we can in our efforts nationally.

18 MS. GARREN: **I'm** Donna Garren from Boskovich
19 Farms. This is kind of a statement to statements that might
20 have been made here. I can't say I represent the whole
21 produce industry, per se, being from Boskovich Farms, but
22 some of the comments that were made, such as developing
23 minimum bacterial counts for produce, I have a problem with,
24 just based on the fact that maybe other countries do have
25 minimums for their bacteria. One, we don't know what those

1 **minimums** are based on, based on scientific facts. If
2 **minimums** were put into the document at this point, without
3 **factual** knowledge of where these counts came from, I just
4 **have** a problem with that. It may be that, meeting those
5 **certain** minimum requirements for certain produce
6 commodities, we may be getting rid of a lot of natural
7 **background microflora** that's present there to spoil, you
8 **know**, the produce, per se, before pathogens, such as
9 opportunistic pathogens, take place and grow and
10 proliferate. So I think more science-based should be not
11 just because other countries are doing it, that we should do
12 it. **This is** a statement made, basically, on minimum
13 **standards** for **microgrowth** or presence of microbiology,
14 **micro**.

15 Also, putting references of certain technologies
16 that we have or should be available to us, such as chlorine
17 alternatives to us, I don't think should be put in a
18 guidance document. I don't mind have a section where you
19 say that there's references that you can go to to obtain
20 alternatives to chlorine, or something to that **effect**, but
21 actually putting certain technologies into the guidance
22 document -- these people are going to use this guidance
23 document to help them develop programs in their companies.

24 To actually have technologies, specific
25 technologies, placed in a guidance document I think may lead

1 people astray, but having a source of information other than
2 the guidance document available to them of the list of
3 possible technologies available to them may be better
4 suited, as opposed to putting it into this document, per se.
5 Thank you.

6 MODERATOR VIOR: Anyone else?

7 (No response.)

a MODERATOR VIOR: Anything from the table?

9 MR. BALDWIN: No.

10 MODERATOR VIOR: Okay. Well, I guess it's my job
11 to wrap this up, and first and foremost, I think, is to
12 thank you. You are the principal players in designing this
13 meeting, in trying to get your feedback, your comments. As
14 we heard, I think we listened and made some changes before,
15 and there will be changes, I'm sure, for the **following**
16 document.

17 So please take at heart that we do listen to your
18 comments, and we will be addressing them in the guidance
19 document. Transcripts will be made available of this
20 meeting, and so we have the transcription service today.
21 I'd like to thank you all for taking the time to be with us
22 today and giving us your comments. They're very important
23 to us.

24 On a separate note, I want to thank the staff that
25 made this meeting possible, all our staff from headquarters,

1 all the partners and agencies involved in developing this
2 document. I personally would like to thank the staff at
3 this library who made the meeting room available to us at a
4 short notice, and our Los Angeles FDA staff, Robert Rast,
5 and, most **heartfully**, David **Sevilla** of my office, who is the
6 best support, and got a lot of the things we needed done
7 here today done.

8 So I'd like to thank those persons, and, again, I
9 would encourage you, if you did not speak today, if you have
10 an afterthought, as we all do sometimes, please make your
11 comments known in written format. In your packet, there is
12 the Federal Register notice that indicates the Management
13 Branch Office address where you can make those -- where you
14 can submit those. So I would encourage you to do so. Also,
15 check our web site. Things are happening all the time.
16 Thank you once again.

17 (Proceedings in the above-entitled matter
18 were concluded.)

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CERTIFICATE OF REPORTER

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This is to certify that the attached proceedings
before: DEPARTMENT OF HEALTH AND HUMAN SERVICES

In-the Matter of:
FOOD AND DRUG ADMINISTRATION
THE MICROBIAL SAFETY OF FRESH PRODUCE

Case No. N/A
Location: San Diego, California
Date: 5-27-98

were held as herein appears, and that this is the
ORIGINAL transcript thereof for the files of
the Department or Commission:

John Stephen
Reporter

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