

1 UNITED STATES OF AMERICA
2 FOOD AND DRUG ADMINISTRATION
3 DEPARTMENT OF AGRICULTURE
4

5 The Microbial Safety of Fresh Produce
6

7 TOWN MEETING
8
9

10
11 Amway Grand Hotel
12 Pearl and Monroe
13 Grand Rapids, MI 49503

14 Monday, December 1, 1997

15 PRESENTERS:

16 Evelyn DeNike, Public Affairs Specialist, FDA
17 Tom Gardine, FDA
18 Ray Mlecko, District Director of FDA; Chicago &
19 Detroit Districts
20 Bob Hollingworth, Director of National Food Safety &
21 Toxicology Center, MSU
22 Dan Wyant, Director of Michigan Department of
23 Agriculture
24 Les Borquin, Extension Food Safety Specialist, MSU
25 Michelle Smith, FDA
Rick Gomez, Cooperative State Research, Education &
Extension Office

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1 Grand Rapids, Michigan, Monday, December 1, 1997

2 9:30 a.m.

3 ---

4 MS. DENIKE: Good morning.

5 MR. GARDINE: Good morning, Evelyn.

6 MS. DENIKE: Welcome to the first Town
7 Hall meeting, co-sponsored by the United States
8 Department of Agriculture and the Food and Drug
9 Administration on the microbial safety of fresh
10 produce.

11 I would like to begin by introducing
12 you to the people here at the front of the room.
13 Starting at my extreme left, Michelle Smith from the
14 Food and Drug Administration; Les Borquin, the
15 Extension Food Safety Specialist at Michigan State
16 University; Dan Wyant, Director of the Michigan
17 Department of Agriculture; Tom Gardine from the Food
18 and Drug Administration. On my extreme right, Ray
19 Mlecko, District Director of Chicago and Detroit
20 Districts; and Bob Hollingworth from Michigan State
21 University. I am Evelyn DeNike, Public Affairs
22 Specialist at the Food and Drug Administration based
23 in Detroit.

24 On October 2nd, President Clinton
25 announced a plan entitled, "Initiative to Ensure the

1 Safety of Imported and Domestic Fruits and
2 Vegetables." As a part of this initiative, he told
3 the United States Department of Agriculture and the
4 Health and Human Services that we were to work
5 together to produce these Town Hall meetings and to
6 develop a plan to ensure the safety of our fresh
7 produce.

8 So we've begun working on draft papers,
9 and the guide that you got handed today is a draft.
10 It's a work in progress. And we're looking at all
11 kinds of things: Microbial food safety hazards,
12 good management practices associated with water
13 quality, sanitation, hygiene, transportation, manure
14 and municipal sewage sludge. You have to say that
15 slowly.

16 So what we want to do is keep this
17 very, very informal. We are here to solicit your
18 input. Our folks are going to take you through the
19 guide, and then there will be ample opportunity for
20 everyone to comment for the record. When you do
21 comment, we ask that you come to one of the two
22 microphones in the center and please give your name
23 first, so that our reporter can get all this
24 information down. We will have formal proceedings.

25 The restrooms are located -- if you go

1 directly out this back door and straight down that
2 hall, they are off on the right. And
3 Dr. Hollingworth said to make sure you wash your
4 hands before you return to the room.

5 MR. MLECKO: With soap and water.

6 MS. DENIKE: With soap and water.

7 MR. GARDINE: Warm water.

8 MS. DENIKE: Warm water. Do we want
9 double scrubs?

10 MR. GARDINE: And wear gloves before
11 you come back.

12 MS. DENIKE: The address for submitting
13 written comments is out on the registration table.
14 And the time is short. I believe December 19th will
15 be the final day for comments. It will be about a
16 week after the last Town Hall meeting. So those of
17 you that might want to take this information back to
18 your organizations and develop written comments, you
19 need to know that they need to get it to us
20 quickly.

21 We will try and amend the agenda and
22 break for lunch at 11:30, allowing us first access
23 to the restaurants, most of which are on the main
24 floor in this hotel. Hopefully, we can get this
25 turned around in an hour and then continue. As I

1 said, we are going to make this informal and try and
2 get as many comments as is possible.

3 And it is my pleasure now to introduce
4 to you Ray Mlecko, the District Director of Chicago
5 and Detroit Districts. Ray?

6 MR. MLECKO: Good morning. And good
7 morning, Evelyn. And everybody can tell by her
8 remarks that I'm her boss, or else it wouldn't be a
9 pleasure introducing me the way it is.

10 I've spent a lot of my time in Chicago,
11 and it really feels good to be out in the real
12 world, so to speak, and now I know how the people in
13 D.C. feel when they leave the Beltway and come out
14 into the real world. This is a beautiful city here
15 with a beautiful hotel, and I am very happy to be
16 here today.

17 On behalf of the Food and Drug
18 Administration, I would like to welcome you all
19 here. And as you'll find out a little later, this
20 really is a historical meeting. It's one of the
21 first. And hopefully it will be the foundation upon
22 which the other meetings can be built and the
23 program can be developed.

24 Now, as most of you know, under the
25 Federal Food, Drug and Cosmetic Act, it is the

1 responsibility of the Food and Drug Administration
2 to make sure that our food supply is both safe and
3 wholesome. Now, we share this with the USDA and the
4 state agencies and local agencies, et cetera. Part
5 of FDA's role is to try to prevent problems before
6 they occur, before they develop, before they get out
7 of hand.

8 Now, based upon our public health
9 responsibilities, President Clinton charged FDA to
10 take the lead in developing a guidance -- and I want
11 to underline the word, "guidance," I want to
12 emphasize the word, "guidance" -- to assist farmers
13 in minimizing microbial problems.

14 Now, I would like to emphasize two
15 points about the President's initiative. First of
16 all, it's a collaborative mission, it's a
17 collaborative venture. We are including or we have
18 included the U.S. Department of Agriculture, the
19 various state departments, like the Michigan State
20 Department of Agriculture, local people, local
21 health authorities, and you, the public, and you,
22 the farmer, and you, the processor.

23 This is one of six meetings that will
24 be given throughout the United States to try to get
25 your input. We're here to listen to you. Everyone

1 will have the right to speak, to say whatever they
2 would like to, voice their concerns in an atmosphere
3 of openness. In other words, whatever you say will
4 have a value to the folks in Washington.

5 The second thing I would like to
6 emphasize is that we are not here to develop
7 regulations. I think everybody agrees that we've
8 got enough regulations now. We have regulations on
9 the books that have been on the books for fifty
10 years, and we don't enforce. There are too many
11 regulations. But what we are trying to do with this
12 meeting, we are trying to start to develop a
13 guidance document for use by the farmers.

14 As we sit here today, we have two
15 jobs. Or there are two tasks. First, we plan to
16 review some of the major features of the President's
17 initiative on fresh produce, and Tom Gardine will
18 give you the background and will discuss the various
19 forces that have led up to this point.

20 And, secondly, and even more
21 importantly, you have an opportunity to give your
22 input into the draft guidelines which are contained
23 in your packet. These guidelines represent our
24 first stab at the issue. And also, it reflects the
25 preliminary thinking of the FDA and USDA

1 scientists. It also has incorporated the comments
2 from the produce subcommittee of the National
3 Advisory Committee on Microbial Criteria in Food,
4 which is an advisory committee to the FDA. And as I
5 said before, these comments have been incorporated
6 in the information you have in your packet.

7 Now, your comments here today, along
8 with the comments from the other five meetings, will
9 be recorded. We have a court reporter here to
10 record the comments. And these comments, then, will
11 be considered and incorporated, as appropriate, into
12 the final draft. The final draft document will be
13 published in the Federal Register early in 1998,
14 calendar year. And then after they are published,
15 you will have another opportunity to submit written
16 comments concerning your viewpoint of the guidance
17 document. And then afterwards, all these comments
18 will be considered and be incorporated, as
19 appropriate, into the final guidance document which
20 also will be published in the Federal Register.

21 Now, both the final draft and the final
22 document will be posted and can be found on FDA's
23 web site, and our address for the web site is
24 contained in the information packet.

25 Now, I can't emphasize enough, folks,

1 that this is your opportunity to have input in
2 something that may affect the way you do business.
3 If there is something here that you can't live with,
4 something here that you disagree with, it may be to
5 your best interest to make your comments, let your
6 views be known. Because without your input, there
7 is a possibility something might be published at a
8 later date that might not be the best thing for you
9 folks here. So we need your input, we're begging
10 for your input, and we hope that we get your input.

11 And finally I would like to thank
12 everyone for taking time from their busy lives to be
13 here and to participate in the first of these six
14 meetings throughout the country. Incidentally,
15 there are six meetings within the continental United
16 States, and there will be one foreign meeting. I
17 don't know where the foreign meeting is going to be,
18 but maybe Tom Gardine does now.

19 And if there is anything -- if anybody
20 has any questions for me personally, anything about
21 the district or whatever, I will be around all day,
22 and feel free to contact me. Thank you.

23 MS. DENIKE: Thanks, Ray. Now it is my
24 pleasure to introduce someone who is not my boss,
25 Commissioner Dan Wyant of the Michigan Department of

1 Agriculture.

2 MR. WYANT: Evelyn, thanks. I
3 appreciate the opportunity to be here. And let me
4 start out by just welcoming everyone here to
5 Michigan. Those who have come in from outside the
6 state, I welcome you here to fine Grand Rapids,
7 particularly this spot. Look at your schedule, I
8 hope you will take a chance to look around. No snow
9 yet, so we've so far been lucky there. And I want
10 to thank everyone also for attending and being part
11 of this.

12 Ray, to you I want to first recognize
13 the outstanding partnership--Evelyn, Ray, Camille,
14 Dr. Gomez in the back of the room--that exists, in
15 my opinion, between the Michigan Department of
16 Agriculture and our federal partners, in addition to
17 our state land grant university. I heard the term
18 "partnership," and we have certainly put an
19 emphasis and focus on maintaining strong
20 partnerships. I believe we've done that with the
21 FDA, USDA, Michigan Department of Agriculture.

22 I want to underline the fact that this
23 is an important discussion, important for many
24 reasons. First of all, it's recognized--and, again,
25 our appreciation to you coming here to Michigan--

1 fruit and vegetable in particular, agriculture in
2 general is very important to the state of Michigan.
3 It's our state's second largest industry. It is a
4 \$37 billion industry. And certainly a major
5 component of that is our fruit and vegetable
6 industry right here today in Grand Rapids in the
7 front end of our annual court show or trade show.
8 It's a fairly big show here for us in the state.
9 So, again, a very timely discussion.

10 Important for the second reason, and
11 that is food safety is absolutely a priority for all
12 of us in the food and agriculture industry, whether
13 you are on the farm, in food processing, retailing
14 or ultimately consuming the food that is produced,
15 not only in this state and this country, but around
16 the world. So we all know, as I look around the
17 room, because we have a lot of our agriculture
18 leadership here today, that food safety has been a
19 front burner issue and a priority for us and it is
20 important to the consumer.

21 It is also important to us to be
22 involved in the food and agriculture industry
23 because, again, without a high degree of consumer
24 confidence, we are not able to market and sell what
25 we grow and produce. So, again, I think there is a

1 general recognition of that, and, again, underline
2 the importance of that.

3 I appreciate and do want to say that --
4 I want to emphasize, too, the fact that FDA/USDA has
5 come in and said that they are prepared to work with
6 industry and work together in a partnership. They
7 are giving assurances the President's initiative
8 will be scientifically based. And, again, it is not
9 intended to cause an economic burden on farmers in
10 particular. And so, again, as we sit here today, we
11 will be anxious to look at some of the discussion,
12 because, again, with that as a focus, we can
13 appreciate that direction and that directive. So
14 we're anxious to do that.

15 We in Michigan, as I said, have been
16 very conscious of the food safety concerns. We've
17 had some very visible experiences with hepatitis A,
18 most recently E. coli in apple cider. Again, I want
19 to emphasize there's been an outstanding
20 relationship with our federal partner and with the
21 university to tackle these kinds of problems. So,
22 again, that is our goal here today, so we keep that
23 foremost in mind.

24 We have attempted here in this state
25 again to provide some leadership on this issue--our

1 food safety alliance, our food safety awareness
2 campaign, in addition to our new initiative that we
3 call Project SAFE, Special Action for Food
4 Emergencies, that tries to coordinate on a state
5 level interagency responsibilities, and one that
6 we're moving the university into and certainly will
7 involve our federal partners as we move forward.
8 And I would be remiss not to recognize, again, the
9 National Food Safety and Toxicology Center at
10 Michigan State University.

11 We think that just adds a wonderful
12 resource to this state. That will allow us in
13 Michigan to continue to be leaders in addressing
14 this very important issue of food safety. So let me
15 stop there. And I appreciate you coming to
16 Michigan, making this one of your stops. It is
17 absolutely a critical issue. I don't think you will
18 find this group hesitant to respond and give you
19 input, and certainly what you don't get today, you
20 are guaranteed to get an adequate amount of input
21 from the state of Michigan as you move forward in
22 this process. So again, thanks for coming.

23 MS. DENIKE: Now I am delighted to
24 introduce to you Bob Hollingworth, who is the
25 Director of our National Food Safety and Toxicology

1 Center, brand new, at Michigan State University.

2 Bob?

3 MR. HOLLINGWORTH: Thank you, Evelyn.
4 And on behalf of Michigan State, let me welcome you
5 to this meeting. And I appreciate the chance to say
6 a few words on behalf of the Extension system, but
7 also I was asked by the Director of Agriculture
8 Experimental Station, Lynn Gray, to include him in
9 this message, and so we will do so.

10 The Director of our Extension program,
11 Arlen Leholm, sends his apologies for not being able
12 to attend himself. He had other business that was
13 pressing, but it seems reasonably appropriate to me
14 to represent him in view of our brand new center
15 that we've developed in the area of food safety,
16 which is just -- this is just the kind of issue that
17 this was established to help work and resolve.

18 Obviously, everybody's become aware
19 over the last few years of the rising number of
20 incidents of human pathogenic microorganisms getting
21 into the human food supply and causing, in some
22 cases, fairly serious human disease problems, and
23 some of those have been quite close to home. We are
24 very familiar, even in this area, with the hepatitis
25 problem in strawberries. Dan Wyant alluded to

1 E. coli getting into cider. And we've also had a
2 problem in this state with bean sprouts, Cyclospora
3 raspberries, et cetera. These have become almost a
4 weekly or sometimes daily headline in the paper over
5 the last couple or three years. Some of these
6 incidents arise overseas, as far as we can tell, but
7 some of them arise closer to home. And those in the
8 business and processing area for fruits and
9 vegetables are working to try to ensure this doesn't
10 happen.

11 Some involve new and more dangerous
12 strains of all pathogens. Sometimes they involve
13 things that are rather exotic and have not been
14 familiar to us before originating outside the United
15 States. Some of these incidents are isolated, but
16 they do have serious health impacts, and they also
17 have serious financial implications for the
18 producer. So it's entirely timely and appropriate
19 that this kind of initiative start to arise and to
20 get some input from the people who do the production
21 as to how we can minimize the problem.

22 So, clearly, Michigan State's very
23 happy to work with MDA and FDA and USDA and probably
24 any other DA that has an interest in this whole
25 situation in developing and disseminating good

1 agricultural practices to decrease this potential
2 problem with microbial contamination. We
3 particularly support the concept of using an
4 educational rather than a regulatory approach to
5 solving this particular problem.

6 And the only thing I would feel it
7 important to point out is that you can only develop
8 good agricultural practices if you have a pretty
9 good sense of what the origins and potential
10 solutions to the problems are. And I would just
11 point out, we have a lot to learn yet about the
12 scope of these microbial contamination problems--
13 production systems that are most at risk, where
14 microbial contamination in produce comes from, how
15 it survives, what conditions favor its spread and
16 what are the best critical control points to work on
17 to minimize the problem.

18 Probably to do this properly, we are
19 going to have to develop ways of testing for
20 contaminating organisms and also that allows you to
21 test the effectiveness of control measures that you
22 have taken to decrease the problem. So it would be
23 wise to spend some time investigating these issues
24 before we can develop really detailed and effective
25 programs. I would say that we have a lot more

1 ignorance than we have knowledge of this situation
2 at the moment.

3 Anyway, I look forward to hearing the
4 discussion that ensues out of this document. We
5 have got some very good people in the audience who
6 know the Michigan production systems for fruits and
7 vegetables intimately, and they are going to have a
8 chance to comment. And we look forward to that and
9 also to the role that MSU can play in this
10 partnership in terms of research, outreach and
11 educational programs for developing a safer system.
12 Thanks.

13 MS. DENIKE: Thank you, Bob. Well,
14 without further ado, Tom, we are going to turn it
15 over to you for the review of the President's Import
16 Food Safety Initiative. We don't call this PIFSI,
17 do we, with the acronym?

18 MR. GARDINE: I might, but that would
19 just be sloppy language.

20 MS. DENIKE: All right.

21 MR. GARDINE: Good morning, everyone.
22 I hope you all can hear me with this mobile mike.
23 First, I would like to respond to some of the things
24 that have been said so far. Ray mentioned the
25 international meeting. I would be very delighted if

1 I had the opportunity to travel to some exotic
2 place, but the international meeting is scheduled
3 for Washington, D.C. next Monday, across the street
4 from the building where I work, so I will miss that
5 opportunity. But it is intended to focus basically
6 on the concerns of the international community
7 through their emphasis and any trade organizations
8 in those countries that wish to travel to the United
9 States. As I said, I recommended Acapulco, but no
10 one was listening.

11 You heard Dan mention that we want this
12 document to be pragmatic. To take -- to give
13 guidance as to what the grower and processor of
14 fresh produce can do to preserve safety of the
15 product and the market acceptance of the product. A
16 key point to remember is that the U.S. government is
17 stressing to the American people to eat fresh
18 produce. I believe the National Cancer Institute
19 has a recommendation of five servings a day. Fresh
20 produce is good for people. We want them to eat it,
21 we want them to enjoy it, and we want it to be as
22 safe as possible. So together, once again, this
23 cooperative effort between the grower and the
24 federal agencies and the states to develop guidance
25 that might pragmatically be helpful in this area,

1 but which must be doable for the grower, and that's
2 the sort of advice we are trying to solicit today.

3 You have a document in front of you. I
4 know if you are like me you had other things to do
5 over your Thanksgiving weekend than to sit down and
6 read it in depth. That's why we are going to try to
7 cover it with some detail this morning to give you
8 some ideas to respond to. But what we want from you
9 are comments as to is this doable, will it be
10 helpful, where we are totally aware that document,
11 that guidance is totally off the mark, where perhaps
12 you, as a grower and industry, want -- might value
13 more detailed guidance when and if it can be
14 developed. We want your input.

15 As a number of people have said, this
16 is a guidance document. It is not a regulation. It
17 does not have the force of law. It is not intended
18 to. It is intended to give the grower concepts that
19 the grower should consider in their operation to
20 minimize microbial hazard with fresh produce. We at
21 the FDA, the USDA and the states and you all realize
22 that we do not live in a sterile world. The earth
23 you plant your crop in, the sky around it is not a
24 sterile environment. The best we are hoping to do
25 is to minimize microbial hazard on fresh produce.

1 One other thing before we start the
2 slide presentation. I have been somewhat sloppy
3 lately and have in casual conversation been
4 referring to this as a regulation. If I do that, my
5 colleagues at the table promised to throw something
6 at me, but I want to stress, if I do misspeak, it is
7 simply misspeaking and does not reflect in any way a
8 hidden agenda on the part of anybody to make this a
9 mandatory regulation, and it is intended to just be
10 guidance.

11 So if we could turn on the lights --
12 turn on the slide and hit the lights.

13 First of all, a little bit about the
14 President's initiative, the initiative to ensure the
15 safety of imported and domestic fruits and
16 vegetables, but you have heard this referred to as
17 PIFSI for short. On October 2, as you heard, the
18 President announced the directive, and he mandated
19 the USFDA and the USDA to develop guidance to
20 industry -- not new regulations, not new
21 requirements, but guidance for consideration of
22 industry to minimize the risk from -- of microbial
23 hazards in produce.

24 If you've had a chance to look at the
25 regulation yet, you know it is really focusing

1 strictly on microbial hazards. The elements of the
2 President's initiative are basically two. There is
3 a legislative component and an administrative
4 component. The basic part of the administrative
5 component is the guidance to industry, but there is
6 also a budget request. We will get that out of the
7 way very quickly. The budget request is likely to
8 happen, if it happens, for the federal government's
9 FY '99 budget, so there is nothing we could tell you
10 about it yet. We do not know what increased
11 resources, if anything, will come to either agency
12 to implement this. We expect some, we do not know
13 what they will be.

14 The legislative proposal, which has
15 been submitted -- by the way, it was sent forward to
16 the House and Senate by Secretary Shalala, I believe
17 November 13th. It has a sponsor in the -- let me
18 focus that a little better -- no, we can't.
19 Camille, could you see if you could focus that. It
20 has sponsors in the House. I do not yet know if it
21 has a sponsor in the Senate. It gives FDA the
22 authority to halt food imports from countries whose
23 systems do not achieve the U.S. level of
24 protection.

25 Well, what does that mean? Does that

1 mean we're going to apply this guidance document to
2 foreign countries when we do not apply it
3 domestically? No, it does not. It is guidance for
4 us. It is guidance for foreign countries. But this
5 does give us the option. If there are risks
6 associated, known risks associated with foreign
7 produce, and we can show that it is truly associated
8 somehow with the agricultural practices in those
9 countries, it gives us an option to limit the access
10 of that product to the U.S. market.

11 Would we do that first? Probably not.
12 We will probably work with countries in an
13 educational mode, as we will work with our domestic
14 industry in an educational mode, as our first step.
15 But if people's health is at risk, here is another
16 tool for the Food and Drug Administration to use.

17 It says here the legislation would
18 provide FDA authority similar to USDA regarding meat
19 and poultry. This is a bit of an exaggeration. We
20 have no intention of requiring registration and
21 preapproval of shipments of food products into the
22 United States. We are simply pointing out that USDA
23 has the authority to stop food shipments when they
24 are produced under a system that does not meet their
25 -- the U.S. government's requirements.

1 They, of course, do require approval
2 almost on a plant by plant basis. I believe we have
3 absolutely no intention of doing that. And after
4 consultation with the Office of the Trade
5 Representative, we believe that this proposed
6 statute is consistent with free trade principles.
7 What the statute would look like if it is ever
8 turned into law, we do not know. The legislative
9 process is just beginning.

10 The administrative components. As you
11 heard, FDA in cooperation with the USDA is to issue
12 within one year, as a final document, guidance for
13 good agricultural practices, GAP's, for the
14 production of fresh produce, and guidance for good
15 manufacturing practices for the processing of fresh
16 produce; i.e., fresh cut produce as an example. And
17 FDA and USDA are to work together to coordinate
18 assistance and educational activities to domestic
19 and foreign industry. Obviously, we are just
20 beginning to go down that road. It's difficult to
21 plan an education program for a document that is, as
22 you heard, nothing but a working draft at this
23 point.

24 We will repeat this many, many times
25 during the presentation. It is guidance; not a

1 regulation. It is intended to help firms, growers
2 and producers identify appropriate practices to
3 minimize microbial hazards, try and identify where
4 pathogens can get on fresh produce, ask that the
5 grower evaluate his practices -- his or her
6 practices in these areas, and perhaps where science
7 exists, give some concrete suggestions and advice as
8 to what a grower could do, given the constraints of
9 his or her operation.

10 What you have in front of you, the
11 guide, is a broad-scope document. It is intended to
12 be applicable for most produce operations. It is --
13 it consists of general areas where we believe
14 microbial contamination can get onto produce and
15 areas that are somewhat within a grower's control or
16 where there are things that a grower can do to
17 minimize the risk within the constraints of his or
18 her operation.

19 It is going to be a very public
20 process. We had a public meeting to kick off
21 discussions on November 17 in Washington. As you've
22 heard, this is the first of a series of grass roots
23 meetings or Town Hall meetings that will occur
24 around the country this week and next. We are
25 trying to go to major agricultural areas. It is, of

1 course, impossible to go to them all, but we think
2 we have a very good schedule to allow us to get
3 input from most of the major growing areas at these
4 regional meetings.

5 There will be one international meeting
6 in Washington, as you heard, intended to get input
7 from our trading partners. Imported produce is
8 very, very important to this industry and to the
9 American public. The amount is growing, and in some
10 cases approximately one-third of the fruits and
11 vegetables that we might ingest in this country is
12 being imported.

13 One other challenge facing us is a
14 proposal to--after we get this broad scope document,
15 which we believe has a great deal of universal
16 applicability--to develop specific GAP's and GMP's
17 for four fresh fruits or vegetables during FY '98.
18 Those have not yet been determined as to what they
19 will be. We intend to go out with the Federal
20 Register document, both soliciting suggestions and
21 asking for any guidance documents that have been
22 prepared by industry or academia in these areas to
23 assist us in considering candidates for specific
24 good agricultural practices, specific to a certain
25 crop. And then to perhaps identify further ones for

1 specific documents in later years and somewhat down
2 the road.

3 This shows that I was up late last
4 night looking at my slides (upside down screen).

5 This is to show you that the major
6 component--once the good agricultural practice
7 document is, indeed, finalized--is for USDA and FDA
8 to work together to assist the domestic grower
9 through outreach and education programs.

10 Let's hope I didn't do this on all of
11 them. (Right side up screen comes into view.) Thank
12 God.

13 One other thing about the public
14 process is the goal right now is sometime in late
15 January or February to publish the draft working
16 guidance that we received today in the Federal
17 Register as a proposed guide--not a final document--
18 with a 45-day comment period. After we absorb the
19 comments we receive at these grass roots meetings
20 and which we receive in writing, we will evaluate
21 them, as you heard, and incorporate them in this
22 draft. There will be another opportunity at that
23 time for people to comment on the draft guidance and
24 for us to review these comments before any final
25 document is published.

1 A little bit very quickly about how --
2 the challenges facing us on imported produce.
3 During this fiscal year, in FY '98, we had hoped to
4 select foreign countries and products to be
5 evaluated. We have to determine what criteria we
6 will apply in this area--volume, importance to the
7 American consumer, association with illness, perhaps
8 risk associated with certain agricultural practices
9 in foreign countries. These all have to be studied
10 and determined as to -- to help us determine which
11 countries to evaluate.

12 We have to evaluate how to best use FDA
13 and USDA resources. USDA's already overseas in the
14 Extension Service and APHIS and have a lot of
15 knowledge that we have to share and work together.
16 FDA has a lot of knowledge from its experience in
17 testing of produce as it comes into the country. We
18 have to plan for sampling in FY '99. Depending on
19 what resources we receive, prepare a protocol for
20 foreign country evaluations and develop profiles of
21 countries to work on country evaluations.

22 We plan to do -- just as we planned to
23 work extensively domestically with U.S. industry on
24 education and outreach, we have to do that with our
25 foreign trading partners, and we will be working

1 with international organizations and consultants to
2 develop non-FDA training, because neither we nor
3 USDA can possibly do it all.

4 And the President challenged us to find
5 ways to better increase or improve our border
6 surveillance. Increasing border surveillance
7 doesn't necessarily mean collecting more samples.
8 We want to look at this in terms of outreach to the
9 foreign countries, although there will be a
10 component of increased border sampling in terms of
11 evaluating how successful we have been in outreach
12 to our foreign trading partners.

13 Before I continue, are there any
14 questions for clarification? As I said, we have a
15 lot to cover. I have no intention of talking for
16 two hours. I am going to be going very fast. Are
17 there any questions of clarification about the
18 President's initiative at this point?

19 MR. HOLLINGWORTH: If I could ask one
20 question. I don't want to divert you from this too
21 much, but will there be a reciprocal increase in
22 monitoring of produce in the United States that
23 matches the increase in monitoring of overseas
24 produce? I mean, is that part of the trade equity
25 situation?

1 MR. GARDINE: We can do things
2 differently here in the United States, in that
3 through the Extension Service and state agencies, we
4 are in a position to work with the farmer closely
5 and have alternate ways to evaluate improvement or
6 to see if the good agricultural practice documents
7 have effect.

8 Will there be market basket type
9 surveillance activities as a measurement to see how
10 serious the microbial problem with fresh produce
11 is? We -- that decision has not yet been made. We
12 may try to do it, but with that, we have the same
13 problem as we do with sampling fresh imported
14 produce for microbiological hazards. The microbes
15 don't spread out, it is a very spotty contamination,
16 and we do not know whether that is the most
17 effective way.

18 As I said, for imports, increased
19 surveillance -- one small component of it might be
20 more samples at the border, but that is not our real
21 goal. We are trying to find better ways to do that
22 job. So it is a possibility not yet determined, but
23 we don't expect that to be a major component of our
24 effort.

25 Ray?

1 MR. MLECKO: How did you know I wanted
2 to say something?

3 MR. GARDINE: Because you pulled the
4 mike closer.

5 MR. MLECKO: Is there any expectation
6 on FDA's part that foreign growers will follow the
7 good agricultural practices?

8 MS. DENIKE: We cannot force foreign
9 growers to do this. We believe it is to their
10 benefit. We have had some contact with their
11 agricultural attaches in Washington. They are, of
12 course--as domestic industry is--somewhat concerned
13 with the implications of this guidance document.
14 But most of our major trading partners that have
15 spoken to us appear willing to look at the guidance
16 and consider it, which at this point is all we can
17 ask. The answer is there is no answer at this
18 point.

19 MR. MLECKO: Thank you.

20 MR. WYANT: Tom, this is what I've
21 heard you say: These are sort of guiding
22 principles, if you will, scientifically based,
23 pragmatic, educationally focused, not regulatory,
24 and consistent with free trade principles. And I
25 think I've heard you say also utilizing the states'

1 existing networks and partnerships.

2 MS. DENIKE: Correct.

3 MR. WYANT: Whether that be Extension
4 Service, whether it would be utilizing the
5 partnership between the USDA, FDA and the state
6 departments of agriculture or whatever the local
7 regulatory arm would be. Am I correct in that to
8 this point?

9 MS. DENIKE: So far, yes.

10 MR. WYANT: Anything else you would
11 like to add to that list to ensure that?

12 MS. DENIKE: No, I think, Dan, you very
13 much covered it. We do not want to recreate or
14 create a new bureaucracy. There are things through
15 Extension, through the state agencies that are
16 working well. We want to work within that
17 structure. We do not want to create a new
18 structure.

19 I would just ask you to introduce
20 yourself for the transcriber, please.

21 MR. GOLDY: My name is Ron Goldy. A
22 couple questions. One is, once you develop the
23 GAP's and the GMP's, will there then be an effort to
24 implement a certified grower-type program?

25 MS. DENIKE: That is under

1 consideration, but at the moment there are no firm
2 plans to do that. It is one of the things being
3 considered to encourage adoption of good
4 agricultural practices, but at the moment it is
5 merely a concept being considered. So the answer to
6 that is we are much too early in the process to give
7 you an answer to that.

8 MR. GOLDY: Again, once those are
9 developed, will there be any additional record
10 keeping on the grower's side that will need to be
11 done?

12 MS. DENIKE: I think as you read the
13 good agricultural practice document, it does not
14 suggest any increased record keeping requirements
15 whatsoever. I think there might be just one -- one
16 area where it is suggested that if you are a
17 packaging house, you may want to consider a pest
18 control log is about the only thing that comes to
19 mind. And you probably should be doing that right
20 now under the good manufacturing practices as they
21 currently exist.

22 Michelle Smith, who is one of our
23 drafters -- Michelle, can you think of any other
24 record keeping requirements being suggested under
25 the guide?

1 MS. SMITH: I think the pest control
2 log is a good example of where there might be places
3 where it would be useful to keep track of what you
4 are doing, whether it's to keep track of the pest
5 control or to have records of employee training in
6 areas of sanitation and hygiene. There is not a
7 specific record keeping requirement, but it may be
8 to your benefit to keep track of what you are doing
9 to make your own process run more smoothly and
10 efficiently. Does that answer the question?

11 MR. GOLDY: And then, finally, what
12 about any kind of spot inspections such as OSHA and
13 other government agencies do? Will there be any of
14 that?

15 MS. DENIKE: At the moment, there are
16 no plans for spot inspection, but I am not going to
17 stand up here and mislead anyone. While we do not
18 anticipate anything like that, we do want to find
19 ways to evaluate the impact of this guidance, so it
20 is a possibility, but not anything that we are at
21 the moment contemplating. But I do not want to
22 mislead you and say under no circumstances will we
23 not. In an attempt to measure the impact of these
24 guidelines, that there is no possibility that that
25 would be something that is done. Not necessarily by

1 FDA, it can be done through other -- you know,
2 through various mechanisms.

3 Stacey? And then we will move on.

4 MS. ZAWEL: My name is Stacey Zawel. I
5 am with the United Fresh Fruit and Vegetable
6 Association as their Director of Scientific
7 Regulatory Affairs.

8 Tom, I just have a couple questions and
9 a couple statements. One of those is that when you
10 said 'sampling,' and we talked a little bit more
11 about it earlier in this question period, I have a
12 great concern that -- of trying to do that, although
13 I also recognize the need to measure the
14 effectiveness of interventions. And the industry
15 has developed this industry-wide guidance, and we're
16 trying to evaluate how, in fact, can we measure the
17 effectiveness of that. So while I recognize that is
18 a difficulty, sampling, as we both know, and many in
19 the room, is a very ineffective way to do so,
20 especially when we know there are some issues out
21 there, and we can't test appropriately, Cyclospora
22 being a very good example.

23 The second question is is there not --
24 you didn't state this specifically, so I want to
25 clarify. Is there not an opportunity to provide

1 written comments to the document right now up
2 through December 19?

3 MS. DENIKE: Yes, this is correct.
4 Since Evelyn mentioned it, I did not, but I believe
5 the Federal Register notice for these Town Hall
6 meetings did mention that written comments -- and I
7 believe, Evelyn, you said the address to send
8 written comments is out on the welcoming table --
9 will be accepted through December 19th.

10 MS. ZAWEL: Right, thank you.

11 MS. DENIKE: And, you know, Stacey
12 makes a very good point, and I think it is just
13 reiterating what I said. We do recognize that end
14 product testing is not the most effective means to
15 evaluate any impact that this guidance document
16 would have, but it is something we are considering
17 among other things to measure the impact.

18 MS. ZAWEL: Okay. The other comment
19 that I wanted to make is one that the industry finds
20 to be very important, and, Tom, you've certainly
21 heard this before, and I direct the comment
22 basically to Mr. Wyant and Dr. Hollingworth in that
23 it's very important, when we talk about foodborne
24 disease outbreaks associated with certain products,
25 that we identify specifically the vehicle that was

1 involved. And strawberries and hepatitis are a
2 perfect example where the hepatitis A caused people
3 to get ill because of consumption of frozen
4 strawberries.

5 And while we cannot determine whether
6 the contamination occurred in a processing
7 environment or whether it occurred in the field to
8 the strawberries, it is very important, especially
9 in light of meetings like that that are public and
10 have opportunities for media to be involved, that
11 very high profile people like yourselves convey that
12 very important information.

13 MS. DENIKE: And let me convey that.
14 At the public meeting, I had a slide talking about
15 illnesses associated with fresh produce, and one of
16 them was hepatitis A in strawberries. And Stacey
17 and her colleagues very rightly pointed out that it
18 wasn't hepatitis A in strawberries; it was hepatitis
19 A in frozen strawberries. I was using that as an
20 example of things that have come to the American
21 public's attention. But we have to admit that in
22 this case certainly and in some others we really
23 don't know where the contaminant entered the food.

24 MR. WYANT: Can I comment real
25 quickly?

1 MS. DENIKE: Last comment, Dan.

2 MR. WYANT: I need to respond to this.
3 I couldn't agree with you more. Ann Veneman from
4 California and I have had detailed discussions about
5 this because, again, we do need to, as much as
6 possible, when possible, like a laser beam, identify
7 the product, because we put the entire industry at
8 risk. Strawberries is a perfect example of that,
9 because the broad base media implicates all
10 strawberries; when, if we can identify not only
11 frozen strawberries, but in addition to that, that
12 we know the frozen strawberries that are at risk are
13 quarantined and in certain locations, then we've got
14 to be able to convince people that -- and as we get
15 more sophisticated in our approaches, hopefully we
16 can even do a better job, so we don't put the entire
17 industry at risk.

18 MS. DENIKE: And, Dan, to save me a few
19 minutes because that was pretty much my closing
20 remark, but I may use -- I may use it anyway.

21 Now a little bit about the guide that
22 you have in front of you today. A little bit about
23 the general concepts. As you've heard, recent
24 outbreaks have raised concerns about the safety of
25 foods, including fresh vegetables and fruits that

1 are not processed to eliminate pathogens. That
2 slide is up there to remind us all of the risks
3 associated with fresh produce. They are not
4 processed in a plant, they are not cooked in the
5 consumer's home; they are eaten as is when purchased
6 by the consumer. And we -- and you as processors do
7 have a certain responsibility to take prudent and
8 doable steps to minimize the risk of microbial
9 contaminants on fresh produce.

10 Not subject to steps to eliminate
11 microbial pathogens, and, therefore, you have to be
12 careful in controlling them.

13 The potential vehicles for pathogenic
14 contamination that we talk about in the guide are
15 water, manure and municipal sewage sludge, worker,
16 field and facility sanitation and hygiene, and
17 transportation. As you look at your guide, you will
18 see there is a section on each of these. This is
19 basically the design of the guidance document.

20 The guide is intended as guidance only,
21 should you not have gathered that already. Growers
22 are urged to take a proactive role in minimizing
23 food safety risks. And at this point, we at FDA and
24 USDA want to tip our hats and thank industry groups
25 such as United Fresh Fruits and Growers, Western

1 Growers, and a number of others who began working on
2 industry good agricultural practices. Certainly we
3 at FDA did, and whose thoughts and documents we have
4 certainly borrowed from heavily in the documents you
5 have in front of you. And what you are reading in
6 that guidance is the best advice of FDA and USDA in
7 consultation with industry and consumer groups, and
8 that consultation is growing and will be increasing
9 in the future.

10 Now that we have a document to talk
11 about, we are having these Town Hall meetings, and
12 we will be having further consultations with
13 industry, academia, and consumer groups about the
14 guidance.

15 The document, as I stated, is broad
16 scoped. It focuses on what we believe are common
17 elements in growing, production and distribution
18 that should be common to most fresh fruits and
19 vegetables. And it is intended -- the guidance in
20 it is intended to reduce the risk of microbial
21 contaminations. There are certainly other things
22 you could talk about in good agricultural
23 practices. This is a very narrowly-focused guide on
24 microbial contamination.

25 We recognize, as you've heard from some

1 of the speakers this morning, that there are many
2 gaps in the science that leads to uncertainties in
3 the degree of risk associated with certain farming
4 practices. That is why in our guidance we talk
5 about minimizing risk. Whenever we have identified
6 these gaps, we try to identify them in the guidance
7 as clearly a suggestion, but areas where further
8 research is needed, and one of the components of the
9 President's initiative is to fund further research
10 to close these gaps.

11 We want the advice to be practical. It
12 has to be something that's doable. That is why we
13 are here today. You must look at it, read it and
14 say it makes sense, it can be done, or, "My God,
15 people, what world do you live in?" This is what we
16 want to hear from you. And as I stated, research
17 will be accelerated under the President's
18 initiative.

19 In some areas, the guidance points out
20 that under no circumstances does the guidance
21 document obviate or eliminate the need to comply
22 with existing state, federal or local laws and
23 regulations. Some of these are on the books. The
24 guidance document does not eliminate the need to
25 comply with the law as it is written now. For

1 example, we must point out that packing houses
2 frequently, as an example, fall under FDA's good
3 manufacturing practice regulation document, which is
4 located in 21 CFR 100, I believe.

5 A little bit about the guide. We
6 believe there are common potential vectors for
7 pathogens--manure, water, worker sanitation,
8 facility sanitation and transportation. Once again,
9 that is how the good agricultural practice document
10 is designed. But we do recognize that there is
11 enormous ranges in farms and facilities available,
12 the climate, the soil that you must deal with. The
13 guidance document will frequently say, "where
14 feasible, based on local conditions and operations,"
15 but we expect, if a grower is going to use this
16 guide, he or she will have to tailor it to his
17 operation. The guide is not a one-size-fits-all.

18 Once again, we recognize cultural
19 practices differ. They do differ. And here is the
20 -- here is what we have to answer today. How can
21 we best provide practical concrete advice to growers
22 that will move us towards safer produce without
23 being unnecessarily costly to growers? Once again,
24 as you review the document and consider making
25 comments, that's the basic question USDA and FDA

1 want you to help us answer.

2 Specifics in the guidance document.
3 Once again, we recognize certainly at this first
4 meeting people did not spend the Thanksgiving
5 weekend researching this, or at least hopefully many
6 of you did not. We will go through very quickly
7 some of the specific statements in the guidance
8 document to give you something to think about
9 perhaps over lunch and come back and comment on.

10 Once again, first part of the document
11 talks about water, water as a vector of microbial
12 pathogens, and what you should be concerned about.
13 We are concerned with water in two aspects. As an
14 inherent source of contamination itself. If the
15 water is contaminated with pathogens, it may place
16 those pathogens onto produce. And, if you take
17 clean water and use it inappropriately to wash
18 contaminated produce, it might spread that localized
19 produce, depending on where -- spread those
20 localized pathogens, depending on how you use the
21 water.

22 Here are some of the pathogens that
23 have been and are referenced in the document
24 associated with water.

25 Because of water's potential as a

1 source of pathogenic microorganisms, growers should
2 carefully analyze practices involving water. The
3 first thing you have to do under the guide is find
4 out where your water is coming from and are you
5 using it appropriately, and then think about how you
6 could limit the possibility for waterborne
7 contamination on fruits and vegetables.

8 You must recognize the potential for
9 water as a source to contain pathogens, and the
10 water you use should be of sufficient quality for
11 its intended use. "Sufficient quality," is not
12 defined in the good agricultural practice document.
13 And if anyone wants to give suggestions on how it
14 can be defined, we would very much appreciate that.

15 Growers should identify the source of
16 water used in different operations. The source of
17 water will vary with the intended use. The quality
18 that is necessary will vary with the intended use.
19 And, once again, what a grower can do is limited,
20 based on the water sources available to them. We
21 don't expect the impossible. The water you have is
22 the water you must work with, and if you can make
23 certain aspects of it better, we ask you to consider
24 it. But if you are working with river water,
25 downstream from a cattle farm, that's what you have

1 to work with, and that's what we want you to
2 evaluate, consider, and see if there are things that
3 you could do to control and limit the pathogens
4 associated with water. And once again, the guidance
5 does not preempt any applicable federal, state or
6 local regulations about the quality of water.

7 Growers should identify and review the
8 source of water used on the farm, step one. As the
9 degree of water-to-produce contact increases, so
10 does the need for good quality water. The more
11 water which is a potential source of pathogens comes
12 into contact with the produce, the more important it
13 is to be cognizant of this danger, be aware of it,
14 and see what can be done to limit any potential for
15 hazards or any contamination, if they exist.

16 Review may include determining whether
17 the source of water is from a well, open canal,
18 reservoir, reused irrigation water, a municipality
19 or other sources. Depending on where you get your
20 water, you have different options as to what you can
21 do to try and control its quality.

22 Controls may include many options such
23 as delaying water use until water quality improves.
24 But if you have to irrigate your crops, that's damn
25 hard to do. Water treatment is an option.

1 Alternative application methods that avoid water-to-
2 produce contact, if that is possible for you,
3 depending on the needs of the crop. Maintaining
4 alternative water supplies, if that is a
5 possibility. The feasibility of these or other
6 controls will depend on the intended use of the
7 water and the needs and resources of a particular
8 operation. We do realize that the options available
9 to many growers will be limited in this area.

10 Irrigation water. Many factors
11 influence a grower's choice of irrigation system:
12 The economics, the water availability, the
13 characteristics and cultural requirements for
14 particular crops. Depending on the crop, growers
15 may need to consider using water delivery systems
16 such as drip irrigation that minimize direct water-
17 to-produce contact for certain produce. Rather,
18 this is just a possibility, a suggestion, something
19 for you to consider. But if water is judged to be a
20 potential hazard for your operation, one thing you
21 should consider is are there ways to limit the
22 contact of the water to the produce. Certainly that
23 should be considered the closer you get to harvest.

24 For crop protection sprays. Water used
25 to mix and load pesticide sprays should be

1 considered a potential source of pathogens. One of
2 the things -- no one has yet solved, for example,
3 the problem you've heard about this morning with
4 Cyclospora in Guatemalan raspberries. But one of
5 the things that is being considered as a potential
6 source was that we noted some of the farmers, in
7 order to protect their primary water supply, their
8 well water that was of sufficient quality when they
9 were mixing their crop protection sprays, would go
10 down to the river and use that, and then spray that
11 on their crop. Something that perhaps if they
12 thought about it a bit more they may not have done,
13 and this is something for you to consider. Be
14 careful as you are mixing your crop protection
15 sprays.

16 Wash water. Safe and sanitary water is
17 recommended for use in washing produce in the field
18 and the packing environment. Once again, water has
19 a potential to add pathogens to the product. It
20 also has a potential -- we think of wash water as
21 something that eliminates problems for us, and,
22 indeed, it is if used properly. But we must
23 remember that washing improperly may take a
24 localized contamination and spread it. So care and
25 thought must be given to the use of wash water.

1 Wash water even with sanitizers may reduce but not
2 eliminate pathogens on the surface of produce. If
3 pathogens are internalized, washing has even less
4 effect.

5 If pathogens are not removed or
6 inactivated, they can spread, so a significant
7 proportion of the produce is contaminated instead of
8 sporadic items. Once again, washing may compound
9 your problem if not done properly instead of helping
10 you solve it.

11 For wash water, you may want to
12 consider chlorination. If done properly, and it's
13 something possible to do with the crops you are
14 working with, it can help you control microbial
15 pathogens in water.

16 Cooling operations. Water and ice used
17 in cooling should be considered a potential source
18 of contamination. Water that comes in contact with
19 the produce is a potential for contamination. Any
20 source of water, any use of water must be
21 evaluated. Growers should be aware of the water
22 source used to make ice and follow practices to
23 reduce the risk of contamination during cooling
24 operations.

25 Water is a vehicle for spreading

1 localized contamination. That's just -- backing
2 that up, that is just a reminder. Water, you must
3 remember, wash water, any kind of water, we think of
4 it as something to help solve our problems, and,
5 indeed, if used properly it is. But if used
6 improperly, it might only compound our problems.
7 Please consider its use very carefully.

8 Manure and sewer sludges. Health
9 officials and scientists agree that animal manure
10 and human fecal matter represent a significant
11 source of human pathogens. Bottom line, and no one
12 I think will disagree.

13 The use of manure or municipal sewage
14 sludge in the production of produce must be closely
15 managed to limit the potential for pathogen
16 contamination of produce. Growers must also be
17 alert to the presence of human or animal fecal
18 matter that may be unwittingly introduced into the
19 produce growing and handling environment.

20 Properly treated manure and sewage
21 sludge is necessary for your operations in many
22 cases. Improperly treated manure or sewer sludge
23 may contain pathogens that can contaminate the
24 product, and as you heard, ruin potentially your
25 marketing potential for a year when people start

1 getting sick. We do recognize that municipal sewage
2 sludge is not widely used on fields growing fresh
3 produce; however, in addition to the potential for
4 untreated sludge to serve as a source of
5 contamination, properly treated municipal sewage
6 sludge has been shown to have beneficial
7 agricultural uses. We realize it's not used a great
8 deal, but it's something that we wanted to talk
9 about in our guidance document.

10 Sources of fecal contamination include
11 the use of untreated or improperly treated manure;
12 nearby composting or treatment operations that are
13 not properly controlled; nearby livestock or poultry
14 operations; nearby municipal wastewater storage or
15 disposal areas; high concentrations of wildlife in
16 growth areas. These are all things which in the
17 guidance document we ask you to consider and
18 evaluate their impact on your operations.

19 Growers may need to develop and follow
20 good agricultural practices for handling manure to
21 reduce the potential for introducing microbial
22 hazards to produce. Practices may include processes
23 such as composting to reduce the possible levels of
24 pathogens in manure. Minimizing, to the extent
25 feasible, direct or indirect manure-product contact,

1 especially close to harvest. The closer the product
2 gets to the consumer, the more care you should
3 exercise. Assessing adjacent or nearby land uses to
4 determine risks from animals that may shed pathogens
5 that can cause contamination.

6 This is just to show that we realize
7 and discuss in the document various treatments to
8 reduce pathogens in manure before use, but we talk
9 mostly about composting. Composting refers to the
10 managed process in which organic materials are
11 digested aerobically or anaerobically by microbial
12 action. Properly composted manure can be an
13 effective and safe fertilizer and/or soil
14 amendment. But it is a controlled process; one that
15 as a grower you should evaluate and make sure it is
16 being done properly.

17 While the agencies USDA and FDA may not
18 have sufficient data to make specific type and
19 temperature recommendations--and we do not in the
20 guidance document--that would apply to all
21 composting or other manure treatment operations,
22 good agricultural practices in this area may reduce
23 the risk of microbial cross contamination from
24 manure to fresh produce.

25 For untreated -- use of untreated

1 manure, growers may reduce the risk of contamination
2 from untreated manure by maximizing the time between
3 application and harvest. Once again, you must
4 increase your concern the closer you get to the
5 consumer. Recommended minimums generally range from
6 40 to 60 days before harvest, and some
7 recommendations are 120 days or longer for the use
8 of untreated manure on fields.

9 The treated product -- treated
10 manure/natural fertilizers, such as composted
11 manure, may need to be produced in a manner to
12 reduce the likelihood of introducing microbial
13 hazards.

14 Care should be taken to avoid cross
15 contamination of fresh produce from manure that is
16 in the process of being composted or otherwise
17 treated. It should be a controlled process.
18 Likewise, improperly treated or incompletely treated
19 manure may also be a source of contamination. If
20 you are going to treat it, you should try working
21 through Extension to treat it properly and learn
22 what must be done.

23 Composting and other treatments may
24 reduce but they may not eliminate pathogens in
25 manure. Furthermore, it is unknown to what extent

1 pathogens that survive treatment may regrow in
2 composted manure. But for that reason, to the
3 extent feasible, you may want to use the same
4 recommendations that we have in the guidance
5 document for untreated manure, essentially
6 maximizing the time between application and
7 harvest. Simply because it's been composted does
8 not mean it is free of pathogens. More research is
9 needed in this area.

10 During composting you should secure the
11 manure or compost to prevent cross contamination of
12 your fields by runoff, leaching or wind spread.

13 MS. DENIKE: Tom, it's almost 10:30.
14 Why don't we take a 15-minute break here and give
15 you a rest and then resume.

16 MR. GARDINE: Okay. Thank you.

17 MS. DENIKE: We will come back at
18 quarter of.

19 (Break was taken from 10:30 to 10:46 a.m.)

20 MS. DENIKE: Thank you all for coming
21 back after putting up with me for over an hour.
22 We're close to the end, and I've asked Evelyn to
23 stop me no matter where I am at a quarter after
24 11:00 so we could have questions of clarification on
25 the guidance document before we go into our lunch

1 break, which may help generate some questions and
2 comments for the afternoon.

3 The next part of the guidance document
4 deals with sanitation and hygiene. Worker health
5 and hygiene play a critical role in the controls to
6 minimize microbial contamination of produce. The
7 bottom line is the fecal-oral diseases and the
8 fecal-oral route is one of the primary concerns with
9 pathogens getting onto produce and spreading
10 disease.

11 Among the control of potential hazards
12 is personal health of the agricultural worker. Good
13 hygienic practices by all workers are essential in
14 the controls of microbial hazards. Infectious
15 disease, ill health with diarrhea, open lesions, et
16 cetera, are a source of microbial contamination and
17 can be transmitted to produce. This is the sort of
18 thing that the manager, the grower, supervisor
19 should be looking for in agricultural workers,
20 whether in the packing house or in the field.

21 Among the comments or suggestions and
22 advice in the guidance document is that an employee
23 should report to a person in charge any information
24 about their health or activities as they relate to
25 diseases transmissible through food. The person in

1 charge should be aware and monitor the health of
2 employees. And individuals with diarrheal disease
3 should not work with fresh produce. We know that's
4 a hard thing to say, and it's a very hard thing for
5 a grower/packing house operator to discern, but
6 basically it's the bottom line of any food handling
7 operation.

8 All employees who are involved in the
9 harvesting, packing and distribution of fresh
10 produce should be trained in good hygienic
11 practices. Let's remember this product is going
12 directly to the consumer. There is no cooking step
13 that's going to be there to protect the product.
14 You are a food -- you are producing a food, and some
15 of the concerns that are more traditional in a
16 retail or manufacturing operation should be
17 considered and are applicable in the farm
18 environment. You might want to consider
19 establishing some form of training program or
20 perhaps signing on to local or state training
21 programs that might be available to your worker.
22 And the program might include a system to monitor
23 and evaluate -- "compliance" is a bad word here, but
24 to monitor and evaluate the success of any training
25 program.

1 The importance of hand washing. Once
2 again, think of yourself, the growing operation, as
3 a food producer. Washing hands after each absence
4 from the work station--using the bathroom, eating
5 and before coming to work--is very important. Dirty
6 hands -- anything that could contain pathogens, be
7 it water, manure, dirty hands, have the potential to
8 gather and spread germs to the surfaces they
9 contact. Washing hands with soap and warm water
10 helps stop the spread of germs.

11 Employees should be taught proper hand
12 washing techniques. You can't assume they know it.

13 Use of sanitation facilities.
14 Facilities such as on-site latrines and avoiding the
15 elimination of waste outside of these facilities
16 should be encouraged. I think for the second part
17 of that sentence, we probably should say, "should be
18 required in the operation."

19 Some concerns with field sanitation.
20 Toilet facilities in the field. The proximity and
21 accessibility of facilities to harvest crews in all
22 sectors of fresh produce production is important.
23 Workers should have the opportunity to use the
24 facilities when needed. This will help reduce the
25 incidence of workers relieving themselves

1 elsewhere.

2 Assure that the locations of facilities
3 is not near a water source used in irrigation.

4 There can be accidents, there can be leaks. Or in a
5 location that would subject it to potential runoff
6 in the event of heavy rains. Facilities should be
7 provided for all workers.

8 Provide adequate hand washing stations
9 with water, including warm water if possible, that
10 is suitable for hand washing or drinking. Toilet
11 facilities should be well supplied with the usual
12 and maintained in a sanitary condition and in good
13 repair at all times.

14 Examples of good practices to consider
15 are the following: Clean or service portable
16 toilets away from the field, if possible. And as
17 you read this guidance document, you will see a lot
18 of if-possibles and where-feasibles. Dispose of
19 wastes through a subsurface septic draining system.
20 Drain wastewater away from the field or collect it
21 in a drainage tank to be correctly disposed of at a
22 remote site. Once again, anything that could place
23 something that could carry disease near the crop,
24 near the produce, should be evaluated, considered,
25 and if it can be controlled better, you should find

1 a way to do so.

2 Septic trucks servicing the portable
3 toilets should have direct access to the toilets.
4 Locate toilets, where possible, in areas to minimize
5 the likelihood of produce contamination. If you
6 have an accident, if you have a break, things don't
7 work properly, you don't want it uphill from your
8 produce. Consider procedures for containment and
9 treatment of any effluent from a toilet in the event
10 of a leakage or spill.

11 The harvesting precautions. Remove as
12 much dirt and mud as possible from the produce while
13 in the field. Let's not bring it into the packing
14 house where it could be a mechanism to spread
15 localized contamination around the plant. Damaged
16 or muddy cartons should be repaired, cleaned or
17 discarded in an effort to reduce microbial
18 contamination of fresh produce. You do not want to
19 do anything that will add to an anticipated
20 microbial load on the product. Let's remember,
21 we're talking about minimizing risk here. You can't
22 eliminate it, but there are things that are -- that
23 obviously can be done, visible to the naked eye,
24 that you should be doing. You should consider
25 doing.

1 Care is needed to ensure that -- to
2 ensure that produce that is packaged in the field is
3 not contaminated in the process. And in the field
4 or in the packing house, the guidance recommends
5 that inspectors, buyers, visitors, wash their hands
6 and/or wear clean disposable gloves before
7 inspecting produce.

8 Equipment maintenance. A person should
9 be in charge of maintaining equipment sanitation.
10 Keep equipment as clean as possible. Items such as
11 lunches, fuel, tools, et cetera should not be
12 carried on harvesting equipment. Remove
13 contaminants--mud, diesel, grease, et cetera--from
14 equipment daily. While we know you don't expect
15 harvesting equipment to be sanitized on a daily
16 basis, but the same piece of equipment that is
17 hauling manure one minute should not be used to move
18 the crops. And the equipment you do use, certain
19 care should be taken to keep it reasonably clean
20 under the environment that you are working. And
21 personal responsibility is something that you should
22 consider. Someone should be put in charge of this,
23 if possible.

24 In the facility, in the packing house,
25 anything in the process from harvest to processing

1 that makes contact with produce has the potential to
2 contaminate it. We can't repeat that enough, and
3 I'm sure many of you think we have already repeated
4 that enough. But I don't think we can. Poor
5 sanitation in the packing house can increase the
6 risk of contamination of produce and water supplies
7 used with produce. Become familiar with laws and
8 regulations--local, federal, state--describing
9 facility sanitation practices, such as 21 CFR 110
10 may be a good resource to use.

11 Equipment in the packing house,
12 equipment such as knives, saws, blades and so forth
13 should be inspected for defects on a regular basis
14 and replaced as needed. Nothing more than is
15 standard for a food processing facility.

16 Personnel should not use equipment that
17 has contact with produce for carrying other
18 materials. And you should keep the packing house
19 and cooling facilities clean and sanitary.

20 Pest control. We mentioned this a
21 little earlier. Obviously, in the packing house,
22 all animals are a potential source of
23 contamination. In enclosed facilities -- and look
24 at the word, "enclosed" -- the pest control program
25 is recommended. Packing house, processing

1 facilities, and grounds around them should be in
2 good condition to protect from pest contamination
3 inside.

4 The final section in the regulation
5 that deals with an area that may contaminate the
6 produce is transportation. You could do the best
7 possible job in growing, harvesting and packing your
8 product, and if the truck that comes to pick it up
9 is contaminated, if it is a mixed load with other
10 product that may be contaminated, much of your --
11 some of your effort can go for naught.

12 Contamination of produce may occur due
13 to improper practices during handling, loading,
14 unloading, and transportation operations. Wherever
15 produce is transported, the sanitation conditions
16 should be evaluated, especially links between the
17 distribution chain. You should inspect the truck
18 before you put the produce on it, as one example.

19 Cross contamination from other foods
20 and non-food sources and contaminated surfaces may
21 occur during transport. What did the truck haul
22 before it got to your product? Segregate fresh
23 produce from other food and non-food sources of
24 pathogens in order to prevent contamination of the
25 produce where possible. Try to assure that trucks

1 or other carrier sanitation requirements are met
2 before loading produce. Put the product into a
3 clean truck. Keep open communication along the
4 transportation route regarding food safety risks and
5 the need for adequate safety steps.

6 We realize, by the way, that the
7 farmer, the grower is not the only -- to make this
8 work, the farmer or the grower is not the only link
9 in the chain that we have to speak to. And as an
10 aside, I want to stress as part of this initiative,
11 there is an initiative for consumer training and for
12 retail training, and there is a regulation, I
13 believe, by the Department of Commerce for
14 transportation.

15 MS. SMITH: There is at least a
16 guidance document that would be useful.

17 MS. DENIKE: Guidance document. That
18 we need to work with the transportation industry to
19 disseminate and educate them about.

20 One last thing that is -- has been sort
21 of grafted onto this guidance document is a
22 statement on trace backs, and I believe the current
23 term of art is -- Michelle?

24 MS. SMITH: Positive lot
25 identification.

1 MR. GARDINE: -- positive lot
2 identification. Basically, what steps can you take
3 if something does go wrong to limit it as much as
4 possible? This is to your benefit, our benefit, and
5 the consumer's benefit, if we can better identify
6 contaminated product. So we asked growers to
7 consider, where feasible for their operation, their
8 crop, the way it's packaged. Once again, we have
9 been talking about minimizing risk. Fresh produce
10 will never be free of all contaminants. We realize
11 that.

12 Trace backs or positive lot
13 identification won't prevent a hazard, but it can
14 limit the potential scope of an outbreak. FDA, if
15 people are getting sick, will not have to recall the
16 entire crop of apples from Washington state. If we
17 could identify the source of the problem, it will
18 limit the populations at risk. It will lead -- it
19 will help us trace back to the specific company,
20 source or growing field of the problem so
21 corrections can be made by the grower. It will
22 lessen the economic burden on operators not
23 responsible for the problem. And it will be more
24 easily implemented. We realize it will be more
25 easily implemented in some operations than others.

1 Trace back, from a government point of
2 view, minimizes the unnecessary expenditure of
3 public health resources. If there is a way to focus
4 on where the problem occurred, it gets us the
5 ability to protect the public a lot quicker. It
6 will reduce consumer anxiety. It frees consumers to
7 enjoy fruits and vegetables not implicated in the
8 outbreak. And as I said, your government is
9 encouraging this. So operators, we ask that you
10 examine current company procedures to trace, to
11 track from farm to receiver, and operators we
12 recommend should develop procedures and technologies
13 to improve trace back from receiver to the farm,
14 which a lot of that is not totally in the grower's
15 control, but something we are encouraging throughout
16 the distribution chain.

17 An effective positive lot
18 identification system should have as much detail as
19 possible. The documentation of the source of the
20 product, the date of harvest, farm identification,
21 chain of custody, and a mechanism for identifying
22 the product that can follow from the farm to the
23 consumer. So once we identify the bad stuff, the
24 consumer can look at their shelf at home or in the
25 grocery shelf and say this is safe to eat. Okay.

1 We are done. Will you turn on the
2 lights. One other -- I just want to reiterate one
3 comment that Dan made, and it does reflect a lot of
4 some of the concerns about industry that we all
5 share. One of the reasons the President gave for
6 his initiative, not only does he recognize that our
7 produce in the United States is probably the safest
8 in the world, and he wants to keep it that way, but
9 the President's initiative realizes that there is a
10 component of this to protect American agriculture.

11 And one quick story having to deal with
12 the hepatitis in strawberry incident that we talked
13 about a little bit earlier. Once again, it was not
14 hepatitis in strawberries; it was hepatitis in
15 processed frozen strawberries, harvested in Mexico,
16 processed in the United States.

17 The week that happened, my office -- my
18 normal office is the Division of Import Operations
19 with FDA. We were not actively involved because no
20 one knew where the problem occurred. Did it occur
21 in the food service? Did it occur in the processing
22 facility? Did it occur on the farm? All we did was
23 put out an advisory to our field staff saying Grower
24 So-and-so in Mexico may be associated with an
25 incident, you may want to sample his product.

1 Although what good that would have done us, since we
2 cannot test for hepatitis A on strawberries
3 effectively -- there is a methodology, but it is not
4 the most effective in the world.

5 But we had the advisory out so we would
6 be looking at the product. That week I had other
7 issues on my plate dealing with I think raisins from
8 Turkey and heavy metal contamination. And sometime
9 during the week I get a call that I was supposed to
10 respond to. And I got back to the individual very
11 late in the day, and I gave an apology and said,
12 "You know, it's been a very busy week, and right
13 now I'm having a bad time. Please excuse me for
14 getting back to you so late." There was quiet at
15 the end of the phone, and the man said, "Tom, I'm
16 one of the major importers of strawberries from
17 Mexico, and you think you're having a bad week."

18 And what he points out is what we all
19 have to realize. When there is an illness out-
20 break, the American consumer doesn't hear,
21 "processed strawberries," or processed this or
22 processed that. They don't hear, "strawberries from
23 one farmer on the West Coast of Mexico." They hear,
24 "strawberries." They don't buy the product whether
25 it's grown in Mexico, grown in New Zealand, grown in

1 Florida, grown in California. It affects everyone's
2 market share.

3 So by working together on this through
4 applying good agricultural practices, through
5 considering trace back methods or positive lot
6 identification mechanisms, we can work together, not
7 only to make a safer product for the American
8 consumer, but to protect American agriculture.

9 And I think now, questions of
10 clarification. And there were some people wanted to
11 ask questions during the break, and if they are
12 available, now is the time.

13 MR. CARTIER: Good morning. My name is
14 Dennis Cartier. And I was wondering if you could
15 elaborate a little bit on the specific selection
16 criteria that you intend to use for selecting four
17 produce categories that you are going to go after
18 first.

19 MR. GARDINE: A couple of points. One,
20 the four items are not selected. We are going to go
21 out, I believe I mentioned, with a Federal Register
22 document, asking industry, consumers, interested
23 parties to suggest criteria, suggest products that
24 may be considered, and to share with us, if
25 available, any guidance documents that may already

1 have been developed.

2 But what criteria are we currently
3 bouncing around in our heads? One, it has to be
4 something of significant dietary impact to the
5 American public. You would not want to spend a
6 great deal of time by our drafters, like Michelle,
7 doing something like star fruit from Asia. It is
8 not significant, it is not worth it, so you would
9 want to look at something with significant dietary
10 impact.

11 Probably another thing you would want
12 to consider, is it likely to be cooked? You know,
13 is there a potential? I mean, it's produce, but how
14 it is normally eaten is another consideration. You
15 would want to associate with it things like has it
16 been associated with illness outbreaks and what is
17 the risk potential associated with the product.
18 Those are a number of the things we are considering,
19 and I'm sure we will hear a number of more things to
20 consider.

21 MS. DENIKE: Tom, I have a question.

22 MR. GARDINE: Please.

23 MS. DENIKE: It looks like with the
24 combined talent that's in this room, that we have in
25 federal and state agencies, the growers themselves,

1 that if we work together, we might be able to
2 develop something in the way of an educational
3 program that will serve everybody's needs, that will
4 possibly be low cost, whatever that might bring into
5 it. What suggestions do you have? Where do you see
6 this coming into play? How far down the road and do
7 we need to be thinking of perhaps pulling together
8 our partnerships right now?

9 MR. GARDINE: We certainly have to
10 start thinking about it, but let's look at what some
11 of the time frames that have been publicly discussed
12 are for this broad-scope guidance document. We are
13 going through a series of grass -- of Town hall
14 meetings this week and next. At which time we will
15 have to wait for the transcription services to get
16 the transcript with any comments, thoughts,
17 suggestions into us. We will certainly be waiting
18 for any further written comments through
19 December 19, I believe.

20 Our goal is to get this document
21 prepared as a draft Federal Register document
22 sometime in late January or February or sometime
23 during February for comment to solicit further
24 comments from industry. And we usually give a --
25 Michelle?

1 MS. SMITH: 45.

2 MR. GARDINE: -- 45-day comment
3 period. We then have to get these comments, work
4 through them, and see what changes are necessary to
5 the draft guidance. So the earliest that a final
6 document can be published in the Federal Register is
7 probably sometime in mid to late summer, is my
8 guess.

9 We are talking to USDA and the National
10 Association of State Departments of Agriculture
11 about how you consider what steps -- what is the
12 most effective way, what are the most effective
13 tools, who could do what in terms of an outreach
14 program. But it is really tough, Evelyn, to get
15 down to details without a guidance document to talk
16 about. But we are -- we are very cognizant, we
17 don't want to recreate the wheel, and we will be
18 working within existing mechanisms.

19 MR. GOLDY: Ron Goldy again. The
20 document that you gave today, on the bottom of
21 Page 22, I think we need to say that there is going
22 to be an extreme amount of difficulty for growers in
23 monitoring the personal health of their workers.
24 Okay. It makes growers personal health police, and
25 I don't think that that is going to be something

1 that many growers are going to be very open to.

2 And I think that the other thing that
3 is going to happen is that some of these things fall
4 under the guidelines of -- or the jurisdiction,
5 perhaps, of right of privacy for the workers. And
6 then if there is an invasion of privacy, the grower
7 might open themselves up to a discrimination lawsuit
8 because they are being discriminated against because
9 that worker is going to come and he can't work that
10 day. And so because the grower says, "I think
11 you've got something that's going to cause problems,
12 I want you to go home." So I just think there's
13 going to be some extreme difficulties in being able
14 to monitor that, and I don't want this to go by
15 without being able to say that.

16 MR. GARDINE: That is the sort of
17 comment that we are here to listen to, and if anyone
18 wants to expand on that right now or ask any other
19 questions of clarification, please do so. That is
20 -- that is exactly the sort of comment, by the way,
21 that we are soliciting. What will work, what will
22 not work.

23 MR. ROPER: Teryl Roper with the
24 University of Wisconsin. I wanted to expand on
25 that. Much of the harvest labor used for fresh

1 produce tends to be at the lowest rung of the
2 economic ladder. And if they come to work and say,
3 "I have diarrhea" -- they are not going to tell you
4 because they need the employment, they need the
5 income.

6 On the other hand, if there were a
7 means to compensate a grower -- or a harvester who
8 is ill so that they could stay away, then I think
9 you would have a lot of illness. Potential 'flu.

10 MR. GARDINE: If you would stay up a
11 moment. But those points are all well taken. And
12 believe me, it is something that we have heard from
13 other people who have been talking to us. But the
14 flip side of the coin is to simply not say that
15 people with diarrheal illness should not -- you
16 know, should be allowed to come in contact with
17 food. So while these points are well taken and must
18 be considered, you must realize that not saying it
19 implies something else.

20 MR. GOLDY: I would be in favor of a
21 strong educational program for these folks. And I
22 think it would be not only advantageous to the
23 safety of the American food supply, but it's going
24 to be advantageous for the long-term health of these
25 people. And it's really to their advantage to let

1 them understand, not only the risk to other people,
2 but the risk to themselves if they continue with
3 that kind of a practice.

4 MR. GARDINE: Okay. Thank you.

5 MR. NYE: Ken Nye, Michigan Farm
6 Bureau. The specific guidelines that would be
7 developed, how rapidly would those proceed?

8 MR. GARDINE: Michelle, would you want
9 to talk on that as one of the drafters?

10 MS. SMITH: One of the things that
11 we're trying to do right now is we're trying to get
12 the general guidance document as far along as
13 possible, and in the comment process to make sure
14 that we're on the right track. To the extent that
15 we're successful in doing that, then we will hit a
16 point where it makes sense to start working on the
17 more specific documents.

18 Exactly when all this happens is kind
19 of like having a crystal ball, but our best guess at
20 the moment is that when this working draft is
21 revised to be a draft stage, and it is published in
22 the Federal Register, and we have the 45-day comment
23 period, somewhere around there we will also have
24 published the Federal Register notice soliciting
25 comment on ways to identify the individual items or

1 groups of items for the more specific guidance
2 documents. And based on input from that Federal
3 Register notice, we should be able to start working
4 on both kind of in tandem. So we'll have a Federal
5 Register notice asking for input on the specific
6 crops. The general guide will have been far enough
7 along to give us an idea of what direction we should
8 be applying to the individual items once they are
9 selected. I expect that process to be starting
10 early next year.

11 MR. NYE: Tom, I think perhaps it was
12 you, it may have been someone else from the panel,
13 there was a reference made to some kind of a
14 certification process or program; it would be under
15 consideration, anyway. Can you elaborate on that?
16 What are you looking at?

17 MR. GARDINE: In all honesty, we cannot
18 elaborate. I think the point I made, that it is
19 something that is being discussed as a possibility,
20 but I have no details and do not know whether that
21 will be a route we choose to go down. It is simply
22 something that is being discussed.

23 MR. NYE: All right. The document
24 references an increase in food safety health
25 problems with fresh fruits and vegetables. How much

1 of that has been attributed to the production side
2 as opposed to the handling and marketing and retail
3 and final preparation? Has there been a way of
4 separating what's happened at the farm level and
5 what's happening within the rest of that food
6 handling chain? Any comments on that?

7 MR. GARDINE: The only comment I could
8 give is that, one, the answer to your question is
9 no, we have not been able to tweeze it out, except
10 in those instances where perhaps state or CDC
11 actually identified perhaps a food processing worker
12 as the source of the illness. But we do recognize
13 that an increase to some extent is due to the fact
14 that fresh produce is being handled somewhat
15 differently with the expansion of salad bars and
16 like that. We do recognize that, but we have not
17 been able to clearly differentiate what percent of
18 that increase is due to what. And I don't think
19 anyone else can, either.

20 MR. NYE: If the guidelines are
21 intended primarily for production agriculture, what
22 then is in the process or in the works to address
23 fruit and vegetable safety issues in terms of a
24 handling side of this, retail and so on?

25 MR. GARDINE: That is going to be

1 handled through the Retail Food Code and the
2 requirements of the food code. And that is -- that
3 was implemented in the President's initiative of
4 last year, the first food safety initiative, and
5 those programs are likely to hit the ground within
6 the next six months in terms of improvements with
7 our -- with -- in the retail sector.

8 And I will ask if anyone has anything
9 they want to add to that.

10 MS. SMITH: The only thing I would add
11 to that is that this guidance document is -- the way
12 I would look at it is it is more of a new element to
13 add to other elements that go from the farm to
14 table. And as additional areas of concern are
15 identified, if there is not something in place
16 already, then we would look at what's in place
17 rather than reinvent the wheel. Then we could try
18 to determine what is needed.

19 MR. NYE: Thank you.

20 MR. HOLLINGWORTH: Tom, could I ask a
21 question? I think I already know the answer to
22 that, but I'll ask it anyway. I happen to be
23 involved in a project of putting out a new volume on
24 Food and Feed Crops of the United States, which this
25 attempts to list all those things that are grown for

1 human food in the United States. And the last time
2 I looked, there were 380 different crops. You are
3 starting on 4 of them. Do you have any idea how far
4 down that chain of 380 you are going to go before
5 you stop?

6 MR. GARDINE: No, but probably nowhere
7 near 380. I think we will be looking at the big
8 impact crops, and I really can't give a number, but
9 not -- not over two digits and probably the low two
10 digits. And it will take several, several years to
11 get there.

12 MR. THELAN: Curt Thelan with the
13 Michigan Department of Agriculture. I have a
14 general comment that echos the point brought up by
15 Evelyn about maybe better utilizing the expertise
16 within the states and the federal level. I know
17 Michigan, like a lot of states, has developed
18 state-specific practices that deal with some of
19 these issues--water quality and the area of well
20 head protection, manure management, just to name a
21 few. I think the document could be enriched by
22 making a general reference to some of those specific
23 practices that are out there at the state and the
24 local level.

25 MR. GARDINE: As a clarification

1 question, are you suggesting further detail or
2 simply refer people to these other guidances?
3 Because what you don't have -- I believe there is an
4 extensive reference list attached to the document,
5 and are you simply suggesting that we, under these
6 discussions, refer documents such as this to the
7 reference list and suggest that people refer to
8 them?

9 MR. THELAN: I would think in a
10 document of this sort, it has to be general in
11 nature, so probably a reference would be a better
12 way to go at it without overburdening it with too
13 much detail in those areas. But I think a reference
14 section would be helpful, at least in giving a
15 producer somewhere to go if he wanted to get those
16 more specific details.

17 MS. SMITH: One of the things we are
18 considering is doing something like that so if there
19 are appropriate state or local agencies that would
20 serve as the contact points for growers looking for
21 more specific information about their region and
22 about state and local regulations, we would be very
23 happy to have names and addresses to include as
24 contacts.

25 MR. THELAN: We will be happy to

1 provide them for you.

2 MR. WYANT: If I can follow up on
3 Curt's point, and I will speak on behalf of
4 Michigan. I notice we have other states here. We
5 all recognize that other states operate differently,
6 and so there is some variety between states in how
7 they manage issues, and food safety being one of
8 those. In Michigan, for example, to Curt's point,
9 we have developed good management practices in this
10 state. They have been approved by our State
11 Division of Agriculture. I mean, we have these
12 working documents that we are working with and then
13 with local teams to implement. And so we have
14 developed a model in this state whereby management
15 practices are developed with the help of the
16 university scientific institutions, but then applied
17 locally through soil conservation districts,
18 extension service, and, again, our local partners,
19 farmers themselves, as peer groups that will sit
20 around and get these practices implemented. So we
21 have got a system in this state on the farm.

22 Now we take that to another level with
23 respect to processing, grocery stores and
24 restaurants. Again, we're a little unique in
25 Michigan because we are one of the few states that

1 have put our food sanitation, grocery inspection
2 into one agency. Most states have public health,
3 Department of Agriculture regulating food handling
4 aspect. We in this state have put that under one
5 umbrella. Again, we have done that to be protective
6 for consistent uniformity and responsiveness. And
7 we think it's gone a long way.

8 I only say that to underline the fact
9 that, again, we have standards and we have programs
10 in place specific. And so, again, we would ask that
11 you look at those or consider those that are already
12 there. Because we're addressing those issues.

13 And then we were talking, Ray, during
14 the break, I don't know of any other states other
15 than California and Michigan that's doing this, but
16 we have added a consumer education component.
17 Again, recognizing that Extension has been doing
18 this for quite some time, but we will be
19 coordinating what the Extension is doing with what
20 private industry is doing, because we also
21 recognize, whether it be Spartan Stores or Kroger or
22 other major retailers, have consumer education
23 efforts in place. We are simply trying to
24 coordinate that in a food safety awareness
25 campaign. So we're one of the few states I'm aware

1 -- I know California is doing it and we in Michigan
2 are doing it, but there may be others. So we again
3 in Michigan try to recognize throughout the system
4 that food safety could break down, and so we have
5 established an initiative, a protocol, where we
6 address those issues.

7 So rather than keep rambling, again,
8 the message here again is please consider the
9 states' ongoing efforts that are already in place
10 that are addressing this issue.

11 MS. DENIKE: And to add to that, this
12 might encourage states that aren't as developed in
13 their process as Michigan is to adapt some of these
14 practices, if states that are doing a good job are
15 highlighted and their materials are made available
16 for others. Because, like you said, Tom, we don't
17 want to reinvent the wheel.

18 MS. ZAWEL: My name is Stacey Zawel
19 with the United Fresh Fruit and Vegetable
20 Association. I want to also emphasize that as we
21 represent many states, and they continue through
22 this entire process to say there is a lot of stuff
23 going on, California has a lot of regulations, and
24 Florida and many other states, including Michigan,
25 and others where this has force of impacting some of

1 the ideas that are presented in here. They impact
2 what the grower can do, because of other agencies
3 that are making some recommendations, and you are
4 going to hear a lot about those different impacts
5 from manure use, sludge use, water use within
6 different states throughout this process, which I
7 think will be very beneficial.

8 I have one question, maybe Michelle can
9 answer. I noticed from the last draft to this draft
10 there was an inclusion that suggested -- actually, I
11 don't have pages for you, but it's under
12 Section 2.2.1 on untreated manure, where there was
13 an addition to the suggestion that NOSB, I believe,
14 makes for organic food production that manure should
15 not be applied within 60 days of harvest. And then
16 this got added, where -- this in the past few days,
17 "minimum recommended intervals for specific crops
18 may be longer, for example 120 to 150 days, between
19 application and harvest for stone fruit." I am
20 wondering what reference that is that supports that
21 statement.

22 MS. SMITH: That came from discussions
23 within the Produce Subcommittee of MACMA. There is
24 not a specific written reference yet. As this is a
25 working document, I felt it was worth including that

1 for discussion purposes. To the extent that we have
2 more support for it or not will decide what happens
3 with that particular statement.

4 MS. ZAWEL: Yeah, and that's actually
5 what I thought, as I was involved in those
6 discussions very closely. And I have a concern,
7 based on the fact that that may come -- may have
8 come from that discussion, that casual mention of
9 something like that could make its way into a
10 document such as this without stronger public health
11 impact recommendations that, in fact, it's been
12 shown that if you don't do this, it could impact
13 public health; where, in fact, that is not at all
14 how the discussion went. And so while it's perhaps
15 a practice, it's going to be very important to
16 support statements like this very solidly with more
17 information.

18 MS. SMITH: We intend to have things
19 appropriately qualified where they appear in this
20 document. We're in the process now of reviewing
21 some of the references that we have received based
22 on comments to previous drafts. And that's an
23 ongoing process.

24 MS. ZAWEL: Yeah, because I think that
25 as you may find through this process in the next few

1 days, that people may be implementing measures.
2 They may not be doing so because it has a public
3 health impact. They may be doing so for many other
4 reasons. And to take that information and include
5 it because it may be a microbiological food safety
6 issue is perhaps of minimal help. And, in fact,
7 when you consider that Organic Food Production
8 recommends 60 days, this applies to many different
9 products obviously, but especially applies to row
10 crops. So if you are going to suggest a 60-day
11 harvest interval for row crops but 150-day perhaps
12 for orchard, tree fruit, there is something that
13 doesn't jibe in terms of parallel risk, in my mind,
14 and that is kind of what needs to go through the
15 process of thinking about some of the inclusions.

16 MS. SMITH: The intent there, for
17 example, with reference to the 60-day is to not say
18 that that is our recommendation, but that is the
19 recommendation of the California Organic Board, and
20 to put it in that context, along with statements of
21 what we do know at this point in time and what we do
22 not know.

23 MS. ZAWEL: Yeah, I know that that's
24 the intent. And the way that we review this
25 document is that while it is a guidance, and I know

1 it is a guidance from the FDA-USDA's standpoint, the
2 content of this is going to be enforced by the
3 industry -- who the industry supplies. So the
4 buyers throughout this country are going to take
5 this document and they are going to say how come
6 your interval is different for stone fruit, why do
7 you use this when this document says 120 days. So
8 it's opportunities like that that could occur that
9 will, in fact, have greater impact on the industry
10 than you intend it to have.

11 MS. SMITH: Okay. I hear the point.

12 MS. DENIKE: I think it's 11:30 now.
13 Let's break for lunch and try and be back at 12:30,
14 and we will resume at that point. Thank you.

15 (Lunch break taken from 11:30 to 12:49 p.m.)

16 MS. DENIKE: Ladies and gentlemen, it's
17 show time. Well, I had to get your attention one
18 way or another.

19 Our next presenter is Dr. Rick Gomez,
20 Cooperative State Research, Education and Extension
21 Service. And Rick is the principal horticulturist.
22 Did I say that right?

23 DR. GOMEZ: You bet'cha.

24 MS. DENIKE: Rick?

25 DR. GOMEZ: Thank you, Evelyn, and good

1 afternoon. I have been asked to tell you what the
2 role of USDA is in this microbial safety of fresh
3 produce. The agency that I come out of is a brand
4 new agency of a couple, three years ago. And it is
5 -- it was created by joining the Extension Service
6 and the Cooperative State Research Service. And,
7 therefore, you got that big long title: Cooperative
8 State Research, Education and Extension Service.
9 But, I will leave that aside for a minute.

10 USDA has and will have a major role to
11 play in this, and some of the agencies that are
12 involved you've already heard about this morning.
13 APHIS, the Animal Plant Health Inspection Service,
14 which is the agency that safeguards American
15 agriculture from foreign pests. They do inspect
16 produce coming in from other nations.

17 Another big player in this role -- in
18 this initiative would be the Natural Resources
19 Conservation Service, which is the old Soil
20 Conservation Service revisited, through the Water
21 and Soil Conservation District. I think we've heard
22 those mentioned, also. So USDA does have a role.

23 My agency, the Cooperative State
24 Research and Extension -- Education and Extension
25 Service, CSREES, is the one that -- the federal

1 partner of the Extension and the experiment station
2 systems through the land grant universities. So we
3 have a mechanism in place to reach down to the
4 county and in the case of Louisiana, parish, level.
5 We do have that educational arm down to that level.
6 We also have many experiment stations throughout the
7 United States that are part of our partnership with
8 the institutions.

9 So we can, in case that there are --
10 and there are gaps in our knowledge. One was
11 alluded to by Tom on some of the manure and fresh
12 manure and so on. We do have ways to address those
13 gaps through research and then through the Extension
14 Service in the educational programs. So USDA does
15 have a role from the outreach and education point of
16 view, and in some cases from the monitoring point of
17 view, such as APHIS.

18 The Natural Resources Conservation
19 Service is also one of the agencies that approves
20 farm plans, farm management plans, and they can play
21 a role in transferring some of this knowledge to the
22 grower.

23 We are definitely working with FDA on
24 this initiative. One of the issues that can come up
25 or will come up is resources. Where are we going to

1 get additional resources if we are going to add
2 educational programs through the Extension system.
3 That is something that we all will have to decide --
4 Tom, and we're looking, you said, FY '99. That may
5 be pushing it on our budget cycle from the USDA. We
6 are already into FY '99, so it may be down the
7 road. But it needs to be addressed. It definitely
8 needs to be addressed. But it can be hooked onto
9 other current initiatives or thrusts that Extension
10 has throughout the states.

11 Water quality initiative is one that
12 comes to mind very, very quickly. We also have
13 several other programs that can be adapted up to a
14 point, such as some of the pesticide programs,
15 pesticide applicator training, and we do those in
16 conjunction with the state departments of
17 agriculture, so we're linked throughout --
18 throughout this whole initiative process.

19 One of the things that I do want to
20 clarify is that we have made statements here this
21 morning and in previous days about CSREES, my
22 agency, monitoring some of the things that are going
23 to happen out in the state and at the producer
24 level. My agency is not a monitoring agency. We do
25 not do that. But we can evaluate the practices that

1 are ongoing in the farm and come back, serve as a
2 feedback mechanism to both FDA and USDA to let us
3 know what is and is not working.

4 How do programs begin in my agency?
5 There are two ways, as usual. From the top down and
6 from the bottom up. We would like to think that
7 most of our programs come from the bottom up, and
8 they do in reality. They address needs of the local
9 level. But once in a while, we have some federal
10 government initiatives, such as this one, that comes
11 from the top down. Those only tend to work when
12 there are additional resources put into them;
13 otherwise, the effort can be minimal if there are no
14 additional resources.

15 But the important part is that the
16 producers at the local level come to us, to the
17 Extension and the experiment station system staff,
18 and tell us what they need, tell us how things
19 really work on the farm. That is our major strength
20 in our agency and in the experiment station and
21 Extension system throughout the United States. And
22 it is a good system. We -- other countries try to
23 emulate our system. So it does work.

24 I think producers, themselves, we need
25 to remember that they eat stuff, also. And they

1 want it as safe as can be. Don't think that they
2 are irresponsible. I think they are the most
3 responsible people that there are. So if we can
4 help them in developing methods and avenues to
5 safeguard our produce more than it is now, they
6 would really appreciate it.

7 One of the things that really happens
8 is that as we develop methods and approaches,
9 programs, they become our partners in the process.
10 And I guess these town meetings are part of that
11 partnership-building process. We have had several
12 commodity groups and we have the departments of ag
13 represented, we have experiment station and
14 Extension people, FDA people both at the federal and
15 local levels and district levels. So we are all
16 represented. And this is the type of partnership we
17 need to encourage to come up with some of these
18 programs to benefit the consumer and us.

19 I do want to leave you with one
20 thought, though. And it has been emphasized, I
21 think Tom mentioned that our produce here in the
22 U.S. is probably the safest in the world. And --
23 but I want to add something. That it is probably --
24 I know it is, more risky not to eat fresh produce
25 than it is from contamination. I want to leave you

1 there. Thank you.

2 MS. DENIKE: Thank you, Rick. We do
3 have some three by five cards if anyone would rather
4 write down a question for a presenter, rather than
5 ask it out loud. That is an option available to
6 you. We are going to go into the questions for
7 clarification now. Anyone with a question.

8 (No response.)

9 MS. DENIKE: No one out there is
10 befuddled or confused about anything? Boy, did we
11 do a good job. Oh, I knew we would get at least
12 one. Thank you, John.

13 MR. TILDEN: I'm always befuddled, so
14 it doesn't surprise anybody.

15 MS. DENIKE: Name?

16 MR. GARDINE: John Tilden with the
17 Michigan Department of Agriculture. Just a question
18 about the process that we are going through and the
19 process that you are going to be using to develop
20 these guidelines further. I guess state and local
21 governments and commodity groups are used to working
22 with managing risks from the chemical risk through
23 the risk management process. There are established
24 guidelines for how to do risk assessments that list
25 mitigation steps. There's risk communication, and

1 we have experience with that. How does that fit in
2 with the process that you are beginning here?

3 MR. GARDINE: Let me start with
4 attempting to answer your question. Of course, as
5 with many things, many of the questions that have
6 been raised, the answers are frequently
7 unsatisfactory because of where we stand here. It
8 is -- the risk assessment -- you notice that this is
9 not, for example, a passive document. It is not a
10 passive document because the science of risk
11 assessment in this area--microbiological
12 contamination on produce--is such that the risks
13 cannot be totally quantified, nor can the control
14 mechanisms.

15 Risk assessment I think is someplace
16 we'd like to go to, but we have a lot of work before
17 we can. So we're at the point of -- you know,
18 minimizing risks where there is science available,
19 but I do not want to pretend we're at a point where
20 we could do satisfactory risk assessment, although
21 that is something that people will be doing research
22 and thinking about a great deal.

23 MR. TILDEN: I will make a pitch here.
24 We are all used to dealing with uncertainties, and
25 we make decisions every day based on limited

1 knowledge. And in Michigan, we just had a
2 phenomenon experience working collaboratively with
3 industry groups and with Extension folks to try to
4 come up with the best solutions we can with the
5 imperfect knowledge that we've got. And one of the
6 things that's been very important has been trying to
7 identify what is known and what is not known. So
8 that we have a shared understanding of where the
9 data gaps are, so to speak.

10 My concern with a document like the one
11 that we have is that there is an awful lot of good
12 recommendations in it, but it doesn't show the
13 uncertainty in there. I think if you had some feel
14 for what we can say emphatically and what we cannot
15 state emphatically, you would have a lot broader-
16 based support for some of the specific
17 recommendations that would come out.

18 We found that early on in our work with
19 apple cider, for example, that we were making
20 recommendations that when we started looking through
21 the published peer review literature, there was
22 precious little to support many of the common sense
23 recommendations. We also found by talking with
24 industry folks that they had a wealth of experience
25 that may not be in the peer review literature, but

1 expert opinion I think is a very valid form of
2 getting information that can be used in risk
3 assessment.

4 I think if we had a structured approach
5 for how we gather this information and how we share
6 this information, it would be a lot easier for all
7 the different stake holders in this process to find
8 a role where we could work together. Because what
9 we found in Michigan is there is an awful lot of
10 common values that we share on this in the area of
11 food safety.

12 MR. KROPF: Roger Kropf, Kropf Fruit
13 Company here near Grand Rapids, Michigan. We are a
14 grower and shipper of fresh apples. Two questions:
15 First one -- and possibly I missed this early on --
16 the dates that you gave for approximately the middle
17 of February for a rough draft and 45 days later for
18 final, is that a drop dead date?

19 MS. SMITH: Now, I think there is a
20 little misunderstanding. Late January/mid February
21 we're anticipating publishing the draft in the
22 Federal Register with a 45-day comment period.
23 Those comments would then need to be evaluated and
24 taken into consideration before a final document
25 would be available later in the year. So there's

1 not going to be a final within 45 days of having
2 published the draft.

3 The other thing about deadlines, when
4 we request comments by a certain deadline, like
5 we're requesting comments from these Town Hall
6 meetings by December 19th, to ensure that your
7 comments are fully considered, you need to make that
8 deadline. But if at all possible, we can still
9 consider untimely comments. We don't -- whenever we
10 can, we try to take into consideration all the
11 useful information we can gather, wherever it comes
12 from.

13 MR. KROPF: Thank you for that. I may
14 have been the only one that didn't understand that.
15 Secondly, when this process of the town meetings
16 finishes somewhere by the 17th or something of
17 December, when this information is gathered, is
18 there a -- is there a way that the participants will
19 have feedback from the other groups that are going
20 to be participating and how the information will
21 flow? Is that going to be a possibility?

22 MR. GARDINE: Could you clarify the
23 question, unless someone else understands.

24 MS. SMITH: I think I understand, and
25 if I don't you can tell me. But all of the comments

1 that we receive -- let me back up a little bit.
2 Transcripts of all of these Town Hall meetings will
3 be made available to anyone that wants a copy of the
4 transcripts. There would be a per page charge, and
5 I don't know all the details, but we could get that
6 information to you.

7 The written comments that will be
8 submitted to Documents from anyone who's interested
9 in providing additional comments, when they have had
10 a chance to take the document home and look at it
11 some more. Those are submitted to Documents
12 Management Branch and they become part of the public
13 record. Documents has mechanisms in place to share
14 those comments with people.

15 MR. KROPF: Thank you.

16 MR. ALMY: I am Al Almy. Tom, this
17 morning you were kind of going over the -- in very
18 broad general terms, the monitoring, if I can use
19 that term, I guess, of practices that growers and
20 the processing community and other nations importing
21 food into the United States conduct. And there is a
22 perception, and I am asking for clarification, I
23 guess, if you are able to, there is a perception
24 that this would mean the United States teams
25 visiting the farms in foreign countries to determine

1 if their production practices are meeting standards
2 that would be acceptable here or equal here to
3 prevent the importation of food that might in some
4 way be contaminated. And that this, in turn, would
5 result in foreign government teams coming to visit
6 U.S. farms. And I think you can understand the
7 apprehension, if there is any truth to this at all,
8 that U.S. growers might have. Could you clarify, is
9 there any specifics as to how the United States
10 might be monitoring the foreign practices?

11 MR. GARDINE: Okay. Number one, I want
12 to stress again this document is guidance, and what
13 is guidance for our domestic industry is equal
14 guidance and suggestions for our trading partners.
15 Nonetheless, we do hope to find out what the
16 agricultural practices are with some of our major
17 trading partners that might contribute to
18 microbiological hazards in produce imported to the
19 U.S., as we are interested in evaluating and getting
20 reports on conditions in the U.S. that might do the
21 same to domestically-grown produce.

22 One of the things that we would
23 consider doing is perhaps visiting and evaluating
24 agricultural sectors with some of our trading
25 partners, but that would have to be done in

1 cooperation with the appropriate regulatory agencies
2 in those countries. How exactly it will be done,
3 how we will develop such a program, how we will
4 coordinate it with the foreign governments, what
5 role international organizations that do this
6 already, such as the Foreign Agricultural
7 Organization, FAO, at the UN, has not yet been
8 determined.

9 But it is highly likely that we will be
10 asking our trading partners for discussions that may
11 include assessment visits in some portions of their
12 agricultural community. Does that mean they will
13 turn around and ask to do the same here? It means
14 they can. Will they? I don't know.

15 MR. ALMY: Thank you.

16 MS. DENIKE: Other questions?

17 (No response.)

18 MS. DENIKE: Seeing none at this time,
19 I would like to take us into the industry group
20 presentations and call on Stacey Zawel of the United
21 Fresh Fruit and Vegetable Association.

22 MS. ZAWEL: Thank you. I just want to
23 make some relatively brief and general comments
24 about the guidance and the process. United itself
25 is a national trade organization that represents

1 over 1,100 growers, shippers, wholesalers and
2 brokers of produce. And I would first like to start
3 by thanking the USFDA and the USDA, who are together
4 developing the guidance for the grass roots
5 meetings, for allowing us to contribute to the
6 process. And we will continue to encourage you to
7 do so, and hold additional meetings in other key
8 produce situations in addition to the six that are
9 being held over the next two weeks.

10 Extensive feedback into any guidance
11 that is intended for the fresh fruit and vegetable
12 industry must be developed with the knowledge of and
13 consideration for what is practical and reasonable
14 to do. And there are a number of areas within this
15 draft guidance -- and I will emphasize "draft" --
16 that are absent of this practicality; for example,
17 covering reservoirs to protect them and putting off
18 irrigation until water quality improves.

19 And we encourage you through the next
20 two-week period, to -- and certainly beyond, to
21 listen to the industry to help shape the guidance
22 towards more appropriate and effective
23 recommendations, because, in fact, the industry
24 itself wants to foster consumer confidence in our
25 products, and we will certainly support efforts

1 which will effectively do so.

2 And the produce industry has spent the
3 past year developing voluntary, industry-wide
4 guidance documents and is well aware of the
5 challenges that are posed by such an endeavor. We
6 have discerned that in many instances there is very
7 little sound scientific knowledge as to the sources
8 of potential microbial hazards in the production,
9 packaging and transportation of produce. And while
10 individual operators put prescriptive prevention --
11 interventions in place, federal guidance should not
12 do so without sound scientific support; and issuing
13 any guidance that suggests impractical
14 recommendations which are not based on sound science
15 or reasonable information would be counter-
16 productive and ineffective.

17 And we certainly fear that the current
18 rapid pace of this effort threatens to marginalize
19 the produce industry participation. It will ignore
20 the complexity of the industry, and it certainly
21 disregards the scientific uncertainty behind micro-
22 biological food safety issues for produce. But, in
23 fact, if the guidance is developed to represent
24 what's practical and what's reasonable and remains
25 within the boundaries of science, and if the

1 education and outreach programs are well thought out
2 and implemented appropriately, then this initiative
3 will be effective. And commodity-specific items
4 will be unnecessary, leaving precious resources to
5 focus efforts where the most benefit can be
6 realized.

7 I want to just encourage that
8 throughout discussions, throughout future documents,
9 future drafts and any media participation that we
10 are all involved in -- and Tom, you did a fantastic
11 job this morning -- it's in the guidance that we
12 encourage the consumption of fresh fruits and
13 vegetables because we continue -- there is an
14 increasing -- there is a rise in consumption of
15 refined foods, along with a rise in chronic disease
16 such as cancer and heart disease. And when an
17 overwhelming -- also, an overwhelming number of
18 scientific studies indicate that we must increase
19 our consumption of fruits and vegetables from
20 anywhere to five to ten servings per day, and not
21 jeopardize the public health by forgetting to add
22 those very important statements, but instead
23 encourage increased consumption.

24 To capitalize on this opportunity
25 throughout the next two weeks, we have gathered a

1 number of industry experts together that represent
2 numerous commodities to convey a number of things,
3 such as why certain practices are followed,
4 demonstrate diversity and complexity of the
5 industry, and also convey what is practical and
6 reasonable and demonstrate that the industry does
7 take this issue of food safety extremely seriously.
8 And I think, Evelyn, you've got the list of the
9 number of industry representatives that are now
10 going to speak. Thank you.

11 MS. DENIKE: Are they going to go in
12 this order?

13 MS. ZAWEL: Yes.

14 MS. DENIKE: Then we would like to call
15 on Roger Kropf, is it? Is that correct?

16 MR. KROPF: That's correct. Again,
17 Roger Kropf, Kropf Fruit Company, Kropf Orchards and
18 Storage. We are growers and shippers of fresh
19 apples here in Michigan. And Stacey is our
20 scientist and our specialist in conversation, and we
21 are just the lay people that come up here to talk to
22 you from the grass roots of where we come from, and
23 we make our living from the soil and growing fruit
24 and selling the produce to the public.

25 And first and foremost in our minds is

1 food safety. We always need to remember and
2 understand that. I have five grandchildren, and I'm
3 reminded every day by these little guys that,
4 "Grandpa, did you wash that?" They are hearing
5 this every day in school. And we push the five a
6 day produce for health, and USDA has supported that
7 dramatically, and the Cancer Society has supported
8 it.

9 We've got a tremendous movement going
10 in this country. And we least not forget that we
11 have the safest food supply in the world now. But
12 there's always room to better ourselves, and we know
13 that, and we can see that, and we're always,
14 constantly working towards that.

15 I guess what I would like to do is
16 share some of my concerns in how we go about
17 accomplishing this. And part of this is that we --
18 we as the lay people need direction in what some
19 measure of guidance for -- do we get an A, B or C
20 for the kind of results that we create for you. Do
21 we -- are we making our food safer? How do we
22 always know that? And that we have to rely on the
23 scientific industry and scientific people and
24 research people to tell us that. We need the
25 scientists. We need the MSU -- all the

1 universities. We need the USDA's running the
2 tabulations of all this so we understand where we
3 stand in this project.

4 And I have a concern that we have many,
5 many levels of different types of food safety for
6 different food products. We have food that's grown
7 in the soil, from the soil, over the soil. We have
8 food that's transported in many different ways, and
9 this is not an easy solution. The reason for my
10 question was there a drop dead date, there is no
11 such thing as a drop dead date when it comes to the
12 food in our industry, and we and our children and
13 grandchildren live on forever. So we hope that the
14 resolution to what we're trying to solve here will
15 be an ongoing process and not something that is set
16 in the next four months, six months, or twelve
17 months. They are going to say, okay, that stuff's
18 going to make us all better for a hundred years.
19 That is not going to happen. We know that.

20 So we have in Michigan some of the
21 finest research and development programs going on
22 here, and safety, of any place in the world--maybe
23 next to California--that has proven that there is a
24 lot of good things happening in agriculture. And if
25 we can utilize already in place the people, the

1 budgets, the money's already allocated, and the
2 expertise that we have to work with, and somehow
3 have that information flow back to us at grass
4 roots, because only that is going to work. It has
5 to be information that we can practically put in
6 place and allow it to happen.

7 And there are things that many of us
8 can do. For example, we do some things in our
9 business. We have gone into quite a major ozonating
10 process, and we ozonate all of our storage rooms
11 where we store all of our apples, and we have found
12 that we are killing everything in that room, so to
13 speak. We don't see molds, we don't see mildews, we
14 don't see any of the bacterial actions. We have
15 nearly stopped the rot processes, because just
16 ozonating the room kills all this bacteria and
17 fungi. And I suspect it will strongly affect some
18 of these microbiological organisms that we're
19 talking about.

20 From there we move on to ozonating the
21 submersion tanks that our fruit goes into when it
22 comes out of storage before it goes down the packing
23 line. But then again, there lies my concern.
24 Because as soon as that fruit leaves our plant, we
25 no longer have control. So there is many levels of

1 control and many levels of restriction areas that
2 can cause problems.

3 I mean, you know, I will talk about my
4 own product so I don't step on anybody else's toes,
5 okay. We have large bulk apple displays in our
6 supermarkets today. And how many times do you pick
7 up an apple that someone else picked up 12 times
8 before you decided that was yours? And that's our
9 life today. That's what we do. But we want to find
10 how we can make it safer.

11 And I want to encourage -- encourage
12 the committee to take all the information and bring
13 their information together from the sources that
14 have the correct abilities to bring us the proper
15 information for us to put into practicality. We can
16 do that for the people. We can do that for the
17 consumers. It's not difficult. But we need to have
18 some guidelines to give us what you want to reach.
19 Do we want 100 percent perfection? Do we want
20 99.999 percent? Do we want 99? We don't know.
21 Whatever that is, we'll do.

22 But it needs to have practical sense
23 and it needs not to take our pocketbooks to the
24 point of no return. At the same time, we don't need
25 to drain budgets that we're going to pay for, also.

1 Because we're double paying this, folks. We're
2 grass roots. We put the monies into the taxes to
3 pay -- to fund the programs, create the programs,
4 process the programs, then regulate the programs.
5 And then we still have to pay the money to make the
6 process work before it ever gets to the consumer.

7 So please consider that in the next few
8 weeks while you're putting this together and please
9 help us to understand where we really need to go
10 with a good final reading that we can all put in
11 practical use. Thank you very much.

12 MS. DENIKE: Thank you, Roger.

13 Tom Graham?

14 MR. GRAHAM: Thank you. Good
15 afternoon, my name is Tom Graham. I serve as the
16 Director of Operations for the Michigan Blueberry
17 Growers Association, also known as MBG Marketing.
18 We are headquartered here in Grand Junction,
19 Michigan. MBG is a producer-owned blueberry
20 marketing, sales and processing cooperative, and
21 have been in operation since 1936. We currently
22 have more than 450 member owners in Michigan,
23 Indiana, Florida and Georgia. Including our
24 marketing contracts, our cooperative represents over
25 750 blueberry producers in seven states.

1 I'd like to begin by stating our
2 disappointment with the organization of today's
3 meeting. It seems nearly futile to have been
4 invited to comment on the draft version of the good
5 agricultural practices guide when we are seeing it
6 for the first time today. Perhaps it was our
7 misfortune to be included in the first of these Town
8 Hall meetings. Attendees would have been better
9 prepared to constructively participate had we had
10 the chance to review the draft guide before today.

11 We strongly support the grass roots
12 effort being exhibited here and do believe
13 government, industry and the American public can
14 work together to reach reasonable and practical
15 solutions to issues such as food safety. Let's give
16 all parties the same opportunity for input. We
17 applaud the initiative to establish a comprehensive
18 guide to help insure the safety of fresh fruits and
19 vegetables and certainly prefer this approach to
20 prescriptive regulation. We hope the final version
21 of the guide will contain sufficient flexibility to
22 recognize the tremendous diversity in food
23 production systems and enough common sense to avoid
24 paralyzing economic constraints.

25 At MBG Marketing, our producers have

1 been committed to good food safety practices since
2 1936. We clearly recognize our products are
3 consumed by people of all ages, and they rely on us
4 to provide healthy, unadulterated fruit. We view
5 our customers' comfort and safety with the same
6 conviction as our own families'. Consumers provide
7 for our economic wellbeing; the least we must do is
8 provide for the safe stewardship of our food
9 supply. Thank you.

10 MS. DENIKE: Thank you. Bob DeBruyn?
11 Did I pronounce that correctly, Bob?

12 MR. DEBRUYN: It's pronounced a lot of
13 ways, and that's probably better than many. I'm Bob
14 DeBruyn with DeBruyn Produce Company. We've been
15 growers and shippers of onions and carrots for 30 or
16 so years, and I have got a lot of experience not
17 only in Michigan but in most of the states that
18 produce those items and some foreign production. I
19 would like to out of that experience give you a few
20 things -- a few ideas of the things that we do and
21 things we do differently in Michigan and things I
22 hope get considered.

23 I, too, have not read the guidelines,
24 and I will try to answer some of the areas that I
25 think you were looking at. First of all, I will try

1 to run parallel, but there are some differences
2 between onions and carrots that start out right
3 away. Onions are dry. They are not particularly
4 temperature sensitive. I think Texas has kept
5 onions at 85 degrees for three months with moving
6 air with no problem. Most onions are eaten peeled.
7 I have never found anyone who likes onion skins very
8 much. And at some point they have been thought to
9 have medicinal benefit; they even rubbed them into
10 wounds in the Middle Ages, as I understand it. Kind
11 of a tearful experience.

12 But, at any rate, carrots meanwhile
13 need to be kept damp, cool, and are quite often
14 eaten in their raw state, which has some bearing on
15 what you can do with them.

16 Michigan grows both onions and carrots
17 on peat or muck type soil. There has been some
18 development of carrot growth on sandy or mineral
19 type soils, but primary production has been on muck
20 soils. And they tend to rotate between carrots and
21 onions, sometimes celery, those kinds of things.
22 This means that the growers tend to use as much of
23 the same equipment as they can--the same irrigation
24 systems, the same spraying systems, all of those
25 kinds of things.

1 Now, obviously, the needs of the crop
2 diverge. You were interested in manure
3 application. As far as I know, somewhere back
4 during the Depression when fertilizer was
5 unaffordable, people tried it and found out that
6 manure was unaffordable because you got no crop
7 quality. And I don't know in my lifetime that I can
8 remember people using manure applications on muck at
9 all. I suppose those deer, when they go out and eat
10 the carrots, leave a little. We try to keep them
11 out. And, obviously, deer don't like onions.

12 As far as irrigation, use of
13 irrigation, at least on the muck crops--clearly the
14 sandy crops or mineral soil have to be
15 sprinkled--has been declining substantially. This
16 is partly I think because we've been hard put to see
17 the benefits, partly because both the Michigan onion
18 and carrot industries are in very precarious
19 economic condition. Another year or two like we've
20 had, and I suspect you will see acreage drop
21 extremely rapidly. We have had two or three years
22 where virtually everybody has been working at well
23 below the cost of production.

24 Anyway, the major way on the muck of
25 irrigating is, of course, to subirrigate by holding

1 the ditches up or pumping water into the ditches and
2 bringing it up through the tile system. We have got
3 to realize that no matter how you irrigate, the
4 crops we are talking about are going to come in
5 contact with the water because they sit on the
6 ground. I don't think you can furrow irrigate if
7 you wanted to on muck, it would all sink before it
8 got to the next microphone, no matter how much you
9 poured at it practically. And drip tape, given the
10 fact that you don't irrigate consistently, then it
11 becomes extremely uneconomic in the situation that
12 we're looking at. That's why people use muck, is
13 because the soil holds the moisture and continues to
14 feed the crop moisture. That's why it's good for
15 celery as well, as Duane and will probably tell you
16 a little later. So we're not given a lot of choice,
17 I don't think, about methods of irrigation.

18 Occasionally irrigation is used for
19 wind control. Once in a great while for cooling.
20 If you are planting carrots, for example, late in
21 the season, and you get some extremely hot days,
22 quite often it's used to try to cool the temperature
23 down to help the emergence, but it has just been
24 declining in its usage.

25 As far as water sources, wells,

1 ditches, perhaps some ponds, there are areas in
2 Michigan where there is no deep well water
3 available. Ditches are practically at that point
4 the only point. I know one farmer who drilled a
5 water well 600 feet, found it filled with salt
6 water, and decided there wasn't water available
7 except through the ditches. We have tested for pH
8 and chemicals. Normally we have relied on
9 governmental sources to test for coliforms and so
10 on, and in my recollection it's not done
11 particularly often, but has been done quite a lot
12 more in recent years. It so happens that we have
13 not had -- or I have not seen bad tests on places we
14 were irrigating, so that's kind of where that would
15 rest, I guess.

16 We don't reclaim water except -- unless
17 you consider that as you irrigate on muck, it goes
18 down, and it comes through the subsystem, and you
19 might pick it up again in the ditch. But I think
20 that may give you some little idea at least on the
21 irrigation and cooling.

22 As far as sprays, Michigan probably has
23 to spray more than many areas because, given the
24 humidity and the fact that we have an awful lot of
25 nice friendly naturally grown weeds, we use more

1 fungicides and herbicides than people that I know do
2 in the west. Naturally, these sprays take water.
3 It's normally from wells, in my experience, because
4 you want water that's pretty clean for a lot of --
5 so it works in the sprayer and so on.

6 Most of the guys now have gone from
7 backflow protectors to separate tanks to make sure
8 they don't feed back into the system. Backflow
9 protectors were the big thing years ago, but this
10 other is newer at this point. I think that will
11 give you some idea on the spraying, anyway.

12 As far as both of these crops are not
13 hand harvested. They are machine harvested, mostly
14 chemically weeded, if you will, or use herbicides,
15 so there are very few people in the field. Michigan
16 had a real fight over a Michigan porta-potty law
17 that was somewhat more stringent than OSHA's, and I
18 think most of the growers here are aware of what's
19 needed and do use those kinds of things if they do
20 have weeding crews and so on, but it is a very
21 minimal kind of activity.

22 When it comes to cooling, onions of
23 course are, if they are cooled at all, cooled pretty
24 much by natural air. And, in fact, I talked to a
25 grower this morning; he's a little nervous that el

1 nino will take away some of the Lord's benefits this
2 winter. Most of the rest of us would probably like
3 that.

4 Carrots. Depending on the grower,
5 carrots can be air cooled; in other words, cold
6 storage room with fans, vacuum sealed. The bigger
7 productions often hydrocool, which then does put the
8 carrots in contact with water. The water is
9 chlorinated. I don't know everybody's regimen for
10 changing the water. Usually there's some continuous
11 flow of water and a continuous flow of chlorine or
12 some other disinfectant.

13 As far as handling, onions are of
14 course not washed, they are brushed. I know of no
15 good way to wash an onion and get -- and have any
16 shelf life left. I think that comes back to
17 normally onions are peeled. Carrots, of course, are
18 washed. They are normally harvested in dump
19 trailers and either with conveyor bottoms or washed
20 out of trucks into carrot pits, and then in either
21 situation they then go into a washing set-up that as
22 far as I know is chlorinated.

23 We're probably a little imprecise on
24 just what level we have maintained over the years,
25 not being sure what level really is accurate other

1 than to judge by the quality of the product.

2 Going back to a point Roger made, most
3 of us probably eat the stuff right out of the wash
4 water, so we're not eager to get sick, but that's
5 hardly a really good guideline, I guess. As far as
6 the pits that carrots are washed out of trucks, we
7 have chlorinated at relatively high levels, simply
8 because one of the real problems with chlorination
9 is that the organic matter absorbs the chlorine and
10 you can throw an awful lot at it and not stay
11 effective too long. There was a time years ago when
12 Michigan State told us we couldn't put enough in to
13 be effective, but we noticed the difference in the
14 quality of the product, and, therefore, have
15 continued to chlorinate in that situation.

16 After the carrots are washed in our own
17 plant, we then have a chlorine dioxide spray after
18 they went on down the line, after they were
19 previously washed, because we were looking for a
20 somewhat longer-lasting benefit other than just the
21 quick chlorine shock.

22 As far as plant clean-up and so on, I
23 think it's probably not uncommon to scrub plants
24 down or hose them down on a daily basis. We usually
25 then at least once a week get a more heavy-duty wash

1 down using disinfectants at some point, but probably
2 not as wildly as you would in a food processing
3 operation, which we had one of those at one point.

4 Training employees. Now I guess it
5 always seemed to me kind of senseless to train
6 employees to wash their hands after they went to the
7 bathroom. We wouldn't have to do that, but our
8 training films did include that type of thing
9 usually along with HACCP training and sometimes the
10 migrant housing training, some of those kinds of
11 things. Because I know I've read the surveys that
12 more people don't than do usually. And in dealing
13 with food, that's fairly important.

14 Monitoring the health of the
15 employees. Certainly no plant doctors or anything.
16 If somebody really looks sick, you tend to send them
17 home. We have been notified a few times about
18 people that had TB, which is -- since I also helped
19 write the state OSHA health regs, I'm finding is on
20 the increase in the country. And normally we try to
21 move those people to a position where the doctor
22 would advise us that that was not a -- that it was
23 not a hazard. And fortunately the medical
24 profession is pretty good about notifying us.

25 Transporting. When you -- when the

1 stuff is harvested in the field, as I've said --
2 I've kind of covered that. Transported normally in
3 farm vehicles or dedicated vehicles that haul
4 primarily that product. In the case of carrots, if
5 you wash them out of the truck, the truck gets
6 washed every time, albeit with kind of muddy water.
7 In a lot of the other cases, it rains a lot in
8 Michigan, I suspect that's the most frequent other
9 cause. Because this stuff is used just on the
10 farm.

11 Onions are transported in bins, wooden
12 bins, dry, on open top trucks or perhaps in bulk
13 trucks. Those again normally tend to only be washed
14 by nature, because you really aren't trying to get
15 the product wet; you are trying to keep it dry and
16 you try to keep those containers dry. They
17 obviously carry some dirt, although muck, when it is
18 dry, is very powdery and goes everywhere you don't
19 want it to go, frankly. So after a while there
20 aren't usually big gobs of mud or something hanging
21 on the thing.

22 As far as outbound trucks, our people
23 on the dock are always instructed if a truck didn't
24 smell right or really looked bad to come get us and
25 we would decide what the carrier had previously

1 hauled, whether there was a reason. Our guys didn't
2 like banana gas and we didn't figure that was really
3 a good reason not to load a truck. On the other
4 hand, we've had some that were -- had been hauling
5 something else, and we would send them to be washed
6 out or rejected. Kind of one of those things that's
7 hard to keep track of, but we have not had a major
8 problem with trucks coming in looking terrible. I
9 think the reason is that, again, Michigan is a great
10 return state to places like Florida where the trucks
11 haul vegetables up, they haul vegetables back, you
12 don't get into the back haul situation. That would
13 most likely happen if trucks were going in some
14 other directions.

15 Identification. We have used a pallet
16 tag system that does real well until the stuff gets
17 on the truck. We can tell which growers and
18 sometimes track it back through the grower to which
19 field the merchandise came from. But when it gets
20 on the truck, you tend to pull the tags because you
21 want the records for your accounting records, and so
22 it doesn't normally go on to the other end, and it's
23 quite possible that we would get loads of two or
24 three growers' produce or something like that.

25 I think that gives you kind of a few of

1 the ideas in the areas that you've talked about,
2 some things that are different in Michigan. I think
3 we have probably, from all I'm hearing, have a lot
4 to learn in the microbiological area. We have gone
5 through a lot of this same process in field
6 sanitation with chemicals. As growers we have done
7 things that we said hell no, we never could do. At
8 the same time, I think government's found that, yes,
9 there were things that hell no, we couldn't do. And
10 only by working together can we find some common
11 ground that solves both problems, and that's the
12 thought I guess I would leave you with. Thank you.

13 MS. DENIKE: Thank you. Duane Frens?

14 MR. FRENS: I am Duane Frens with the
15 Michigan Celery Promotion Co-op in Hudsonville,
16 Michigan. I didn't exactly plan on speaking today,
17 but basically the celery industry in Michigan is all
18 on muck soil, as is the carrot and onion industry.
19 Our growers apply pesticides on a regular basis,
20 using an IBM monitoring program for the most part to
21 minimize the amount of applications and risk and
22 residue. Irrigation is very common in muck with --
23 on celery, using mostly overhead irrigation from
24 ditches, ponds and well water. I don't know which
25 would be the most common. All three of them are

1 used. Usually with the rain, they get about an inch
2 a week during the main growing season.

3 Celery in Michigan is all machine
4 harvested in the field. We do not have field
5 workers. This is different than what it is in
6 Florida, Texas or California. The celery then
7 that's harvested in the field is hauled to the
8 packing sheds, and is trimmed and washed with a
9 high-volume, low-pressure wash, and then is given a
10 final rinse of fresh water, sometimes with chlorine,
11 sometimes without chlorine in it.

12 The cooling is done normally at the
13 shipper, and it's usually just cold air storage,
14 cooling or vacuum cooling. And the product is
15 basically identified on the carton by grower, but
16 not on the product itself at the consumer level.
17 That's the practices that we have in Michigan for
18 harvesting and packing of celery.

19 MS. DENIKE: Thank you, Duane. Our
20 next industry presenter is Jim Miller from the Board
21 of Directors of the Michigan Farm Bureau.

22 MR. MILLER: Thank you very much. Good
23 afternoon, ladies and gentlemen. I certainly
24 appreciate the opportunity to address you today. I
25 am a grower in southwestern Michigan, fruit,

1 primarily peaches and apples, and as you mentioned,
2 I am on the Board of Directors of Michigan Farm
3 Bureau. Again, I want to thank the FDA and the USDA
4 for allowing us this opportunity to address your
5 proposed guidelines, and we certainly thank you for
6 coming to Michigan for your meeting and allowing us
7 this opportunity.

8 In fact, we would thank you basically
9 for looking at this whole food safety issue in the
10 perspective that it appears you have taken, and that
11 is allowing the ag community, the grower in
12 particular, giving him the credit for being able to
13 work through a self-help guideline type program that
14 you have offered. We would again look forward to
15 the final draft of these guidelines, and probably at
16 this point, my comments will be quite brief until we
17 really see what we are going to be looking at in
18 that final draft.

19 But growers certainly do recognize the
20 stake that they have in maintaining the consumer
21 confidence in a safe food supply, and certainly look
22 forward to being able to utilize your guidelines in
23 evaluating their own operations and making those
24 improvements where they can.

25 I would simply say, though, and say it

1 quite strongly, I think Farm Bureau certainly
2 expects these guidelines to stay as guidelines, as
3 you have indicated many times here, and certainly
4 not become regulations, as you have stated.

5 I am going to just touch on two real
6 quick issues, and then my colleague, Dan Hill, is
7 going to address a couple of specifics that you have
8 listed in your guidelines. Mr. Almy asked a
9 question earlier about the inspection proposal of
10 going into the other countries to look at their
11 operations, farms and processing plants, et cetera.
12 And Farm Bureau would certainly have some concerns
13 about any type of activity like that in, you know,
14 visiting another sovereign state and -- any type of
15 activity in that regard that would allow and invite
16 the opportunity for a retaliatory-type response for
17 them to come into our country, we would be opposed
18 to at this point.

19 Plant inspections at the border of our
20 country we feel are very important and would
21 certainly encourage adequate funding to maintain
22 those inspections, increase those inspections, and
23 we feel that inspection at the border is a very
24 viable alternative to moving into other countries
25 and inspecting their operations.

1 Also, being that these are voluntary
2 guidelines, you know, a good working relationship
3 really is going to be extremely important. We feel
4 that the USDA has that working relationship with the
5 agricultural community now. Food and Drug, as I
6 understand, is the lead agency on this. We would
7 think that USDA might be considered as becoming the
8 lead agency on this, particularly if you have, as I
9 understand, indicated there are going to be two or
10 three separate guides farther up the food chain into
11 the retail level. And then there is going to be
12 quite an extensive education, consumer education, a
13 consumer type program, that these guidelines and
14 this initiative here might fall under the lead of
15 the USDA. We feel their relationship with the
16 grower community is very good, and the possibility
17 of a little better implementation through USDA might
18 be possible.

19 Thank you again for allowing me to make
20 these few comments. We would look forward to seeing
21 the final draft. Dan, I am going to ask him if he
22 --with your permission--could address a couple of
23 those specific issues.

24 MR. HILL: Dan Hill. I hope am not
25 speaking out of turn at the moment.

1 MS. DENIKE: No, you're fine, Dan.

2 MR. HILL: I am a grower. I am a farm
3 marketer from the eastern side of the state, a small
4 farm market. We sell direct to consumers. We sell
5 retail, wholesale, pick your own. We cover all the
6 marketing ends. And I think that's one thing I
7 haven't seen really addressed in your
8 recommendations right here. I realize there's
9 several crops you can look at. There's lots of
10 different ways to market, also.

11 We are a third generation family farm.
12 I am chairman of commodities -- Food and Vegetable
13 Advisory Board for Farm Bureau. I am also on the
14 Vegetable Council for the State of Michigan. And I
15 think one thing you've got to get through to the
16 agricultural community is FDA, as we know, is a
17 regulatory agency, not a recommendatory agency.
18 Every time we see something in writing from you
19 folks, we think it's just a regulation waiting to
20 happen.

21 We appreciate the input and the chance
22 to speak on this. And I recognize quite a few of
23 these recommendations -- I went to the Farm Assist
24 program this year, through the Natural Resources
25 Conservation -- get the new name, NCRS. And I

1 recognize a few things from the worker protection
2 standards and a few more from the field sanitation.
3 I think FDA has done a good job of taking the lead
4 and putting these things together, because I opened
5 my eyes a little bit when I went through the Farm
6 Assist program with the water management, and I
7 think it's very valuable for any grower to go
8 through this.

9 And I think at this time it would
10 behoove the FDA to pass those regulations on to USDA
11 and then to MDA, who has done a superb job in this
12 state unifying a lot of those regulations and
13 compliance procedures and inspections into one
14 area. I have had the opportunity to work with MDA,
15 Department of Health and different places with
16 different people coming out to inspect my property.
17 It is much easier to work with my inspector--not
18 that it's easier to buy them off or anything--but
19 they know who you are and where you are. They don't
20 have to call you for directions from the wrong
21 farm. It is so much easier to get to know these
22 people, and they can communicate with the
23 agricultural community on a one-to-one basis.

24 I had a chance to speak with several
25 FDA inspectors this year who came out to see my

1 cider mill. Nicest folks you ever met. But they
2 ask me, do you sell more than one variety of apple?
3 I realize we have a bit of a learning curve to give
4 to FDA; whereas, if USDA and the MDA inspector had
5 come out together, we wouldn't see something that
6 looks like an interagency rivalry. We certainly
7 don't want to have that happen.

8 We have had a good working rapport with
9 MDA, who works well with USDA. And as it is on most
10 farms, we get inspected by MDA, USDA, we have a
11 chance for Department of Labor to come out, but we
12 have a lot of opportunities for different folks to
13 come out. We would like to see that unified, if
14 possible. I think then the message would get
15 through to the agricultural community that these are
16 good recommendations to work with, to work towards.

17 My farm grows a dozen crops or more. I
18 know of several growers that grow more than that. I
19 think when you get into specific recommendations,
20 it's going to end up looking like some of the
21 insurance deals to the government. It takes a long
22 time, and there is a lot of variables, by sending
23 markets different ways they sell fruits and
24 vegetables. You may be stepping into a mess bigger
25 than you can actually finish in a lifetime. I know

1 the insurance people at the federal government have
2 kind of seen that. I know they are working towards
3 something new. But I think the general
4 recommendations as they are are very nice. I think
5 they are very valuable. And I would like to see us
6 work towards staying on a recommendation level on
7 those things, working through the USDA and MDA.
8 Thank you.

9 MS. DENIKE: Thank you very much, Dan.
10 Are there other comments for the record at this
11 time? From anyone? Please identify yourself and
12 your group.

13 MR. DUDEK: Thomas Dudek, Michigan
14 State University Extension, Grand Haven, Michigan.
15 Just a couple of comments or observations.

16 When we talk about the trace-back
17 aspect of it, I think Duane alluded to it in that
18 celery at the consumer level is sold by the stalk,
19 many times it's not in a sleeve, a pepper, a
20 cucumber, tomato, an apple, as Roger had mentioned
21 sold individually. You know, if the end consumer
22 needs to find out if there was a problem with that
23 particular piece of fruit or vegetable, it's not on
24 the sticker. If you are going to go to a -- they
25 are not stickering.

1 And if you go to a sticker, that just
2 jacks up the cost. We've seen that already with
3 squash. For instance, many growers now market hard
4 squash with recipe labels on it, and it adds to the
5 cost of production. It wasn't something they maybe
6 chose to do, but they were forced to do because of
7 marketing competitors doing it. So in order to stay
8 in business, you do it. Here again, you will have
9 to look at that one and see where that end use
10 trace-back comes to the consumer.

11 The other thing was mentioned, I am one
12 of the USDA people from Extension that's going to
13 probably end up carrying out some of this locally,
14 right here in the 5-county area around Grand
15 Rapids. Resources are a concern. I know we don't
16 want to extend more dollars into a program, but if
17 we're going to redirect dollars from something to
18 something else, then, you know, where do we go with
19 that.

20 But resources are very helpful. When
21 we started the pesticide education programs and
22 helped growers do a better job of making sure that
23 they were certified to spray materials, USDA's
24 federal partners came in and gave dollars down to
25 the State to produce the resources and the

1 materials. And that's real helpful. We are going
2 to need those things to do the job, whatever job is
3 going to be done. Whether they are written
4 resources, videos, slides, et cetera, et cetera.
5 There need to be those resources. It helps us to do
6 that. Michigan has been a very good state in
7 putting packages like this together, but they have
8 gotten the resources.

9 The other thing is, since we're dealing
10 in many cases with bilingual people that we will
11 look at targeting these programs towards, we are
12 going to have to have bilingual resources if we're
13 going to be effective. Thank you.

14 MS. DENIKE: Thank you. Somebody else
15 was getting up?

16 MR. FOGG: My name is Ralph Fogg. I am
17 with the Michigan Vegetable Council, and our group
18 and I would just like to tell you a little bit about
19 it. We have about 2,500 vegetable growers that are
20 a member of the organization, all voluntary, and our
21 main purpose is to conduct educational meetings,
22 which we will be doing in January, to try to inform
23 the growers of new practices. And included on the
24 program this year is a food safety session.

25 We have worked with MDA. We have

1 worked with Michigan State University very closely.
2 We have somebody from MDA and Michigan State on our
3 executive board and appreciate the guidance they
4 give us and we've -- I would like to reiterate what
5 Dan Hill said, that we've had a very good
6 relationship between Michigan agricultural
7 producers, the MDA, and Michigan State University,
8 and also USDA. I think these are all people that
9 are familiar with agriculture.

10 When we hear, 'FDA,' I guess I get a
11 little concerned all of a sudden because this is a
12 regulatory agency. I think a couple of things I
13 would like to see you keep in mind is that when you
14 make a guideline, and a suggested guideline, it
15 might often be interpreted as the correct way to do
16 things. And then if there is a problem with a food
17 product, they are going to look up and down the
18 chain and see if everybody following the guidelines,
19 whether they apply to our farm or not. We may be
20 looked at as a person contributing to that problem,
21 and have some liability there.

22 If that's the case, which it very well
23 could be, I think growers are going to look at it
24 and say these are guidelines but they are also
25 interpreted as regulations. We have to comply. And

1 in the process of complying and hiring people --
2 like our farm is a one-horse show. If you want to
3 know who fills out the I-9's, you are looking at the
4 person. And who does the jobs that the workers
5 refuse to do? Well, you are looking at the person.

6 So when a regulation comes along, I
7 have to comply with that. And it gets difficult
8 right now, on our operation, to do all the things
9 that are necessary from a regulatory standpoint. If
10 you come along with more regulations, even though
11 they are guidelines, I am going to have to comply
12 with them. And I think what you are going to see is
13 less people my size and more people of larger
14 operations. And I am not sure this is the direction
15 we want to push things. But this is what
16 regulations do.

17 The idea of tracking is of concern to
18 me because we raise zucchini, and to put a sticker
19 on every zucchini is difficult. And a big buyer in
20 this area is the Meijer store, who buy from us, and
21 they buy from at least three other growers at the
22 same time. So my product is going to be mixed with
23 their product on the shelf. It is going to be
24 difficult to keep it separate. Although I can see
25 why knowing where something came from is going to be

1 a desirable thing.

2 Workers' health. This last year was
3 probably the worst year we've had for working with
4 labor. The labor supply was adequate, but there
5 just seemed to be more indifference towards
6 attendance especially. Diarrhea was the number one
7 reason given for why a worker missed. And I guess I
8 find it a little bit difficult to ask that question
9 of my workers every morning before we go out to work
10 as far as what their health is like, particularly
11 that issue.

12 The water supply we use for irrigation
13 comes from some rivers adjacent to our farm.
14 Upstream from the river is a city called Flint,
15 Michigan. And I don't know what's in that water.
16 Sometimes maybe I think I don't want to know, but I
17 suppose we should want to know. We have never had a
18 problem, but is it my responsibility to know what
19 they are putting in the water on a continuous
20 basis? I should -- I think I should be able to feel
21 that that supply of water is not contaminated by
22 municipalities upstream. And if it is, it shouldn't
23 be my responsibility to monitor that continuously.

24 I guess the other question as we talk
25 about all these different things, I hope somebody

1 someplace says this is what it is going to cost and
2 this is how many people's lives we expect to save.
3 Because if we can't answer that question, then I
4 think we're spinning our wheels, and maybe that
5 should be addressed early on. In my operation I
6 have to do that. I have to have a cost analysis of
7 everything; sometimes it's not too formal, sometimes
8 it's quite formal. And I hope your organization
9 will someplace along the line look at that and say
10 if we implement all these things, here's how many
11 lives we expect to save. And also take into
12 consideration that many of the problems from a
13 health standpoint are deliberate violations of
14 present regulations, that it's not going to be
15 affected by this. Thank you.

16 MS. DENIKE: Thank you. Somebody
17 else?

18 MR. ROPER: Teryl Roper from the
19 University of Wisconsin. I wanted to reiterate the
20 need for funding for outreach activities to the
21 states. While I think the state Extension service
22 is a very warranted program in this area and is
23 willing to work with growers and their employees on
24 these kinds of agricultural practices, we do need
25 resources to do that.

1 Secondly, I am wondering if there are
2 opportunities for cooperation of wildlife management
3 agencies to reduce deer and other wildlife
4 populations in and around fruit and vegetable
5 plants. I think that is a big problem in Wisconsin
6 as well as Michigan. Unfortunately, many of the
7 wildlife management agencies' primary clientele are
8 hunters, recreational use, and they turn a deaf ear
9 to the impact of particularly deer on agriculture.
10 And we may be able to view this as more of a
11 microbial contamination issue than a crop reduction
12 kind of issue. I think there are real opportunities
13 for discussion with the wildlife management agencies
14 on that regard.

15 Perhaps I am in a minority view here.
16 Growers could perhaps view these suggestions or
17 guidelines as protection. If they are doing a good
18 job of following the guidelines once they are
19 established and have been -- the procedure has been
20 gone through to establish them, and if there were a
21 problem, and if they are following those guidelines,
22 they can say I did the very best job I could and
23 there was a problem. While they can't absolve
24 themselves of responsibility for it, they can at
25 least say I did the best job that I could.

1 One of the crops I work with in
2 Wisconsin is the cranberry industry, and that is an
3 unusual industry, and admittedly a small industry
4 related to the overall food chain in the United
5 States. Cranberries are irrigated, and they are
6 largely irrigated from surface waters; in fact,
7 exclusively irrigated from surface waters. For the
8 fresh product in Wisconsin, the fruit are water
9 harvested. Lots of water. Water tends to be
10 shifted from one bed to another as harvest proceeds,
11 because of the large quantities of water that are
12 required.

13 Once the berries are harvested, they
14 are dried, and they are kept dried thereafter until
15 they are consumed. They are perishable to some
16 extent, like strawberries or raspberries, in that if
17 they were moistened again or washed again, once they
18 had been dried, there would be a great opportunity
19 for rot. And, frankly, if you have seen many fresh
20 cranberries in the grocery stores this year, you
21 know about the opportunity for rot.

22 It is really impossible to protect
23 those surface waters that are used for irrigation
24 and harvest. Acres and acres of open reservoir. In
25 fact, one of the reasons that -- one of the

1 advantages of the cranberry industry is that it
2 provides abundant habitat for water fowl, which
3 creates another problem there, because we know what
4 water fowl leave behind. So we need to make these
5 guidelines broad enough to account for very minor
6 crops in the fresh fruit and vegetable area, as
7 well. And those are my comments.

8 MS. DENIKE: Thank you. Would anyone
9 else care to comment? Yes.

10 MS. DECHOW: Mary Dechow from Spartan
11 Stores. Spartan Stores is a grocery wholesaler. We
12 are based here in Grand Rapids, so we didn't have to
13 drive very far, but we do welcome all of you that
14 came from a long distance at the end of this holiday
15 weekend.

16 We supply groceries to better than 500
17 supermarkets in Michigan, Indiana and Ohio. We're
18 the ninth largest grocery wholesaler in the United
19 States.

20 I wanted to offer just a couple
21 comments really on the positive lot identification
22 issue that is dealt with at the end of the document
23 that we received. And coming from a wholesaler
24 standpoint, we can see some real problems with
25 tracking and positive lot identification.

1 And I would welcome any of you to stop
2 in and visit us sometime and see what we do. At any
3 one given time, we could have as many as 400
4 different fruits and vegetable items coming through
5 our warehouse. And, of course, the blueberries that
6 I buy from New Zealand today may tomorrow be coming
7 from Grand Junction. And ultimately from our
8 warehouse they are loaded into loads for various
9 stores and then shipped on to those retail
10 supermarkets where, again, not only are they
11 comingled in my warehouse, but then they end up
12 comingled back at the supermarket level where the
13 consumer buys it and/or she may buy blueberries
14 today and may buy some more next week, so they also
15 end up comingled at home as they are trying to mix
16 the fruit salad.

17 Positive identification all the way
18 through the food chain is truly, truly impossible.
19 Can we identify it from the time that it arrives in
20 our facility? Most certainly can. Because we know
21 who we've bought that from and generally the
22 shipping crates are identified, at least to the
23 packer that packed those. Now, quite often they may
24 not be identified as to the actual grower that grew
25 those, but to the packer that received everything.

1 We do have tracking systems in place
2 and are working on new tracking systems to even
3 better keep control of that and know exactly where
4 things come from. But if I get a call from, for
5 instance, a media person that might say, "We've got
6 an outbreak of something that happened at XYZ
7 Supermarket that we suspect may have had it, and can
8 you tell me where this came from," believe me, Gail
9 Drew, who is with me today, and is our food tech
10 person, can spend hours on end trying to figure out
11 where something came from. And ultimately maybe
12 have a 50-percent guess that we hopefully will know
13 where it's from.

14 So I caution you, as we look at this
15 whole positive identification, to keep in mind the
16 logistics of the whole food distribution system.
17 Recently in the supermarket you have seen more
18 product look-up codes on fresh fruits and
19 vegetables. And we've gotten into that because it's
20 much easier for us to make sure that prices are
21 correct at the front end of the store. The
22 interesting thing that it's prompted is a lot of
23 consumer complaints, because they don't like those
24 little stickers on their green peppers or whatever
25 else they may appear on. And so it becomes -- it

1 becomes a problem.

2 And, obviously, identifying each and
3 every fruit and vegetable as it comes through,
4 because of size, because of quantity and all the
5 other factors is going to be impossible. So I
6 caution you, as you look at that, to make sure you
7 are working with the wholesale industry to see what
8 is feasible and, of course, the growing industry, as
9 well.

10 Thank you for the opportunity to
11 comment and appreciate working with you in the
12 future on it.

13 MS. DENIKE: Thank you, Mary.
14 Additional comments, please? Yes, sir.

15 MR. HOSFIELD: My name is George
16 Hosfield, and I am with the USDA Agriculture
17 Research Service, and I would like to comment on
18 something I don't think has been adequately
19 addressed here.

20 Recently, Secretary of Agriculture Dan
21 Glickman implemented a new activity for USDA called
22 the Gleaning and Food Recovery Activities. Now, I
23 picked this brochure up, I would just like to read
24 something here. Connecticut.

25 "The Connecticut Agriculture Experiment

1 Station, New Haven, provides excess
2 produce from two research farms to soup
3 kitchens and churches in the Hartford, New
4 Haven and Waterbury areas."

5 Now, these are areas--because I'm from the East--of
6 considerable populations. Now, this program that
7 Secretary Glickman is asking I know USDA to
8 implement, represents a non-traditional entry of
9 food into the food consumer chain.

10 Now, under the federal purview, okay,
11 the Agriculture Research Service would be involved
12 in agriculture research as it deals with farm crops
13 and horticultural crops.

14 Now, for example, I am a plant breeder,
15 and I don't know very much about microbiology. And
16 in my department I don't have a food safety program
17 there. So I guess the thing that -- and I am
18 suggesting is somehow that this activity--gleaning
19 and food recovery--be worked into your documents
20 somehow. Because here we are going to have food
21 through a non-traditional mechanism getting into the
22 food chain. So there has to be some precautions
23 with regard to this type of food because there could
24 be -- also could be contamination because it is in a
25 food production system that operates the same way

1 that any grower or whatever has on his own farm, and
2 also with regard to the distribution of it.

3 MS. DENIKE: For point of
4 clarification, are you suggesting, then, for
5 experimental stations that may be donating it, that
6 we apply the same yardstick that we do to a regular
7 grower in the field? A regular grower?

8 MR. HOSFIELD: I think if we are going
9 to protect the food safety of people in this
10 country, we are going to have to.

11 MS. DENIKE: I just wanted to clarify.
12 Thank you. Somebody else? The man in the striped
13 shirt. If you all want to line up one behind the
14 other, we can do it that way and save a little bit
15 of time. I didn't think of it until just now.

16 MR. FALAK: Appreciate the opportunity
17 to come here today. Chris Falak. I am involved in
18 the produce industry, also a member of the Michigan
19 Vegetable Council.

20 We have established here today that the
21 United States has the -- probably the safest food in
22 the world. Nobody--unless I missed it early in the
23 day--has made the comment that it is also one of the
24 most inexpensive producers of food in the world.
25 And the public expects that when they buy it.

1 I guess this goes two different ways.
2 While these guidelines and recommendations are made,
3 we have said common sense plays into it. And that
4 would also play into the fact that if they are
5 common sense, they shouldn't cost nearly as much
6 money on the grower side of things to make that
7 possible.

8 I guess to take it a step further, for
9 the information that is given to the consumer, if it
10 would be possible, when it's passed on to them to
11 indicate to them that somewhere down the road these
12 prices are going to have to go up for us to continue
13 to improve our food safety. Because at the present
14 time, if I am not mistaken, the average consumer
15 wants the safest food, but they don't want to pay
16 any more for it. Thank you.

17 MS. DENIKE: Thank you. Next, please.

18 MR. KARNEMAAT: Kent Karnemaat from
19 Fremont. I am a grower and a packer and a shipper
20 of various fruits and vegetables. I want to thank
21 you for the privilege to come and to listen and to
22 share some concerns. And just a couple things that
23 I think haven't been mentioned.

24 Ralph alluded to the fact that there
25 are a lot of small family businesses that these

1 guidelines will affect. And I think that's very
2 true, and we need to remember that. We are not
3 dealing with corporate America here. This is going
4 to come right back to home.

5 And the second comment I would like to
6 make, as far as the health of the hand labor and the
7 workers who harvest these crops. We employ about 60
8 people in our harvesting season. These people
9 aren't tractors or machinery. They are people. And
10 to meet them in the morning and say, "Okay, Lupe, I
11 think you look a little under the weather. You may
12 have to stay home today," it's not going to happen.
13 We don't work as a manager and as a worker; we work
14 together, okay.

15 And they are going to decide for
16 themselves whether they work that day or they don't,
17 and I am not going to tell them you work or you
18 don't work. And money is very important to these
19 people, and they are not -- if they can walk, they
20 will work. And we need to remember that when we
21 come up with guidelines to try and determine whether
22 they can work today or they can't. They have a
23 family to feed, and I think that's very important.

24 And I would also, just as a question, I
25 wonder how this meeting is publicized to people.

1 I'm very concerned for the number of growers that I
2 see here today, very few are here, and I think the
3 reason being many don't know the meeting is even
4 going on. I didn't know about the meeting until
5 about 8:00 o'clock this morning, and I think it's
6 definitely a concern of many growers, and I hope to
7 speak for many of them. And, once again, I want to
8 thank you for the chance to come and to talk to
9 you. Thank you.

10 MS. DENIKE: Thank you. In terms of
11 notification, we relied a lot on the people in this
12 room to help get the word out. We were on a short
13 time frame. I know the Michigan Department of
14 Agriculture, Michigan Farm Bureau did excellent jobs
15 getting this out. The Extension Service got this
16 throughout the state. I think part of the problem
17 is this comes on the tail end of a holiday weekend.
18 And I think that probably more than any single thing
19 affects attendance. Other comments for the record?

20 MR. WYANT: Evelyn, I would like to
21 make a comment? Do I need to go --

22 MS. DENIKE: No, you've got your own
23 mike.

24 MR. WYANT: I want to speak and I want
25 to get in on this, also, on behalf of the Michigan

1 Department of Agriculture and on behalf of the
2 entire food and agriculture industry. A comment and
3 observations. A comment. And that is I think -- I
4 know that the food and agriculture industry in this
5 state understands the importance of food safety.
6 They absolutely realize that's the cornerstone of
7 their future success. So I think we've got to give
8 some recognition to that, that this industry has
9 been providing leadership in the private sector, on
10 farms, to ensure a safe food supply.

11 I also, though, want to comment to say
12 that we have to continue to do better, because we
13 are going to be asked to do better, whether we like
14 it or not. Again, because the consumer, the
15 marketplace, will dictate that to you. You--those
16 who are involved economically in the industry. So
17 it's again a fundamental fact that it will be,
18 again, as I predict, a cornerstone to your future
19 success.

20 Observations with respect to what I
21 consider to be critical, guiding principles to make
22 this a successful initiative. And again, on behalf
23 of Michigan, I want to thank FDA, USDA and the
24 President for recognizing food safety as an
25 important issue. One, again, that all of us here in

1 this room do recognize of the first and foremost.
2 And it's been said here scientifically-based
3 guidance; again, I can't overemphasize that enough,
4 we've got to have guidance and principles based in
5 sound science.

6 I absolutely think it's critical that
7 it's educationally focused, and not only
8 educationally focused, but that we use current
9 infrastructure and that's state and local team
10 building. Dan Hill said it best. We've got USDA,
11 FDA, MDA, the local Public Health, State Public
12 Health, Extension on your farm today, and so, again,
13 I think our local partners are there to help carry
14 this message out. And it's the most effective way
15 when we use local leadership and local input and
16 involvement.

17 So, again, I again suggest strongly
18 that for this to work, it has to involve our local
19 teams. It's important related to that that we don't
20 duplicate bureaucracies. I see a real risk of that
21 in this process. In other words, some very nice
22 things were said about MDA, but, again, I think a
23 lot of that comes from the fact that we utilize
24 local Extension, we utilize our local team, and I
25 would hope again that FDA understands that, and USDA

1 would understand that. And, again, we don't need to
2 create yet another set of bureaucracy to look at
3 food safety.

4 Certainly we appreciate and need to
5 continue to recognize a partnership as we move
6 forward and work as partners, because FDA has a
7 responsibility. The President has given them the
8 charge. Whether we like it or not, you are going to
9 be involved in that. I just again would ask that
10 for this to work, it has to work in coordination
11 with states and also our local partners.

12 I think that for this to work, I think
13 Bob DeBruyn said this well, we have to be
14 sophisticated enough not only to understand and
15 recognize commodity differences, but also regional
16 differences. I am absolutely convinced that we do
17 things a little differently here than in Florida,
18 California and in Washington with respect to
19 chemical use, manure management, and, again, just
20 our climate and our soils create differences. And
21 we're sophisticated enough, I think in many
22 instances, to recognize those differences, and I
23 think it's important to realize.

24 And then finally one last point I want
25 to make. This absolutely has to be consistent in my

1 mind with free trade principles. Jim Miller and
2 others have talked about this well. In other words,
3 if we create a system where we're creating barriers
4 to trade, I think agriculture's put at severe risk.
5 And so, again, a foundation has to be that we
6 recognize free market, free market principles. And
7 I'm concerned about that, only because I have a
8 bias, and that's where Michigan agriculture's future
9 growth, a lot of it is going to exist, and that's in
10 export trade. Anything that would diminish that
11 export opportunity I think would be detrimental to
12 the Michigan agriculture industry. So I wanted to
13 go on record with those comments. Thank you.

14 MS. DENIKE: Other comments?

15 MR. DEBRUYN: If I may presume to say
16 just a little more.

17 MS. DENIKE: Would you identify
18 yourself.

19 MR. DEBRUYN: I'm sorry, Bob DeBruyn.
20 My observation has been that in Michigan over the
21 years there have been a lot of small producers, some
22 middle producers, and then a few very large
23 producers. The very large producers can do a lot of
24 things that you ask one way or the other. The guys
25 on the bottom, if the rules aren't practical--it

1 comes from some experience with OSHA, field
2 sanitation and some other things--if the rules
3 aren't practical and reasonably well accepted, you
4 will have a substantial group who will market to
5 their own local markets and whatever. They simply
6 don't want to know too much, I suppose, or maybe
7 can't afford to know too much.

8 The really tragic part of that is if
9 that happens, that it means that there's -- it makes
10 it almost impossible for that guy to move up and
11 become a responsible kind of middle group or move on
12 up to the bigger, because the costs are so much
13 higher, that he likes to just stay there, hide, and
14 do what he wants. And I think that would be a
15 really tragic result of regulating something that
16 didn't work fairly practically.

17 MS. DENIKE: Thank you. Next?

18 MR. MCCREARY: My name is Kirk
19 McCreary. I am with MBG Marketing, blueberries. I
20 guess just one observation. You are going to be
21 going around to several meetings in different
22 regions of the country, and I want to compliment you
23 for getting out into the field, so to speak. But if
24 it's not on your agenda, I would certainly encourage
25 you to take that one step farther and get out

1 actually into the field.

2 Today you've heard from several groups,
3 which obviously all have some sort of an agenda.
4 And you had some growers which can describe in part
5 or in full quite well how they are doing it. But
6 until you get out and see how some of these growers
7 have to operate, the kind of labor they have to deal
8 with, the conditions they are working under, the
9 types of water they are using. Going to a wholesale
10 market for example in Chicago or Philadelphia would
11 be an eye opener on how food is handled.

12 I really would like to encourage you or
13 someone from the group that is making these
14 decisions to get out -- stay away from the glossy
15 people, the strawberry people, stay away from the
16 blueberry people -- get out and talk to growers,
17 people who are doing it, mid-size growers perhaps,
18 people who are dealing with this day to day. Find
19 out what their problems are, how they have to
20 operate.

21 See how the food chain works on a
22 practical basis. How does this stuff go on the
23 truck, what happens to this truck when it's going
24 down the road, what happens when it gets to Spartan
25 Stores or to a wholesale distributor in Chicago.

1 And get a firsthand feel for how this stuff is
2 handled. And I think this will do as much to give
3 you an idea, first of all, how it's done now, what's
4 the practical way of impacting food safety, and that
5 should be a very important part of your decision
6 making process. Because, again, if this isn't a
7 practical program that you put together that we can
8 all work with, it's not going to happen. And I
9 think that's a goal that we all have to do. So I
10 again say get out and get dirty and see how it
11 really happens. Thank you.

12 MS. DENIKE: It's time we got a little
13 mud on our boots, huh? It's time we got some boots
14 maybe.

15 Other comments?

16 (No response.)

17 MS. DENIKE: From the table? Michelle,
18 any final thoughts?

19 MS. SMITH: One thing that jumped into
20 my mind, a number of the commenters talked about the
21 difficulties with lot identification. And we fully
22 understand that there are a lot of things that make
23 it very difficult, but -- and so you may not be able
24 to use the laser beam that was mentioned this
25 morning and really narrowing down, but if you make

1 anything more narrow than the broad generalization
2 of 'all strawberries,' you've helped the situation.
3 If you can narrow down the source of produce to a
4 region or even a handful of farms, that's certainly
5 a step in the right direction.

6 And the other thing I would like to say
7 is that I think the input has been very valuable
8 here, and I appreciate the opportunity to have come
9 and listened to it. What we do can only be as good
10 as the material that you give us to work with. So I
11 say thanks.

12 MS. DENIKE: Okay. Tom? Final
13 comments?

14 MR. GARDINE: Well, I don't know if I
15 will be final. I think you are reserving that for
16 yourself, Evelyn.

17 MS. DENIKE: You put me in charge.

18 MR. GARDINE: First rule, a sincere
19 thank you. I came here with a bit of concern. I
20 know there was concern on your part that you didn't
21 have sufficient time to review the document and the
22 point raised by several of you was understood and
23 taken, but we were under some -- we had to get
24 started sometime, and it didn't help to wait till
25 Christmas week, because then no one would come.

1 But I just want -- I was a bit
2 concerned as to the comments we would get, and I was
3 sitting here looking quickly at my notes, and I
4 didn't write down all of the comments, because I was
5 trying to get ready to respond to many of them. And
6 I counted at least five suggestions and ideas that
7 we are going to have to go back and either change or
8 reevaluate in our mind whether what we put in there
9 is appropriate and consider at further meetings.

10 I think any time you have a group like
11 this, a gathering like this, and come away with this
12 minimum of five suggestions and ideas that have to
13 be looked at further -- and I know there were more
14 because, as I said, there were a few I didn't write
15 down as I was trying to get ready to respond. I am
16 so pleased with the participation here, and I am
17 grateful to all of you for coming to this meeting.

18 And, once again, this is intended to be
19 a public meeting. This cannot work without the
20 cooperation of industry. And we will try to keep
21 this process as public as we possibly can. And once
22 again, thank you.

23 MS. DENIKE: Dan, you made your
24 comments already?

25 MR. WYANT: (Nodding head in the

1 affirmative.)

2 MS. DENIKE: Les, do you have anything
3 you would care to say?

4 MR. BORQUIN: Just a couple things
5 since Bob has left. I just wanted to chime in and
6 agree with a lot of things that Dan talked about.
7 MSU has benefited greatly from partnering with FDA,
8 FDA over in the Detroit district, and cooperating on
9 some of the issues that have come up recently.

10 I wanted also to chime in on what John
11 Tilden told us earlier, that we really need to make
12 sure that the recommendations that come out in this
13 document, that we apply some measure of risk
14 assessments to this. Because a lot of these
15 recommendations look to make good sense, but in many
16 cases I think we don't necessarily have a good idea
17 of just to what extent these changes really will
18 have with regard to safety of the final product.
19 That's an area that really does need some additional
20 research in the future, and we would certainly hope
21 that some resources would be assigned to that area
22 in addition to additional support for education that
23 may come out of this process.

24 MS. DENIKE: Ray?

25 MR. MLECKO: I am a government

1 bureaucrat, and I have had extensive, wide
2 experience in the area of drugs and devices. I've
3 spent most of my life in those areas. I don't have
4 that much experience with fresh produce. But I can
5 tell you from my experiences with drugs and devices
6 that if we, all of us, don't make this work, some
7 other country will, and there will go our market.
8 We all have to work together to make this work.

9 Folks, I've seen it happen with devices
10 and with drugs. A lot of people are predicting that
11 in another 20 years, all of our medical devices will
12 be manufactured overseas. And as a consumer, all I
13 have to do is pick up a can of canned mushrooms and
14 it may have -- it may have a U.S. brand on it, but
15 if you look on the other side, you can see where
16 it's coming from, and it's not manufactured in this
17 country.

18 And I predict that unless we can come
19 up with a safe and wholesome product, fresh produce,
20 if we can't do it, some other country will, and they
21 will reap the economic benefits of the product.

22 The other point I would like to make is
23 that the gentleman that talked about the FDA, I
24 agree with him, that we have a reputation of being
25 strong regulators. In the old days, we used to feel

1 that we wore the white hats, industry wore the black
2 hats, and all we could do was seize and cite and
3 prosecute, et cetera, et cetera. That was thirty,
4 forty years ago. The FDA has changed. We now have
5 a number of cooperative programs with industry, and
6 we're great believers today in voluntary
7 compliance. So some of the impressions that people
8 may have of the FDA, that may have been the old FDA,
9 and we are trying to change.

10 And as a matter of fact, President
11 Clinton gave us this very important initiative, and
12 I kind of predict it's going to be made on a
13 non-confrontational basis with industry and with the
14 USDA and with the various state departments. And
15 the only way this country is going to survive,
16 believe me, is if we all cooperate, we all work
17 together. If we can't do that, we are going to be
18 in deep economic trouble as some of our other
19 commodity areas have been in the past. Thank you.

20 MS. DENIKE: Thank you. I am very
21 proud of us here, collectively, in the room. People
22 of goodwill have not forgotten the person at the end
23 of the road: The American consumer. And our
24 responsibility collectively to the consumer to
25 provide the best, most wholesome, most economic food

1 that is possible to produce. And American
2 agriculture is second to none, worldwide, in being
3 able to do this. We need to crank it up a notch and
4 see what we can do collectively.

5 I am proud of the fact that this was
6 guidance, as opposed to regulations. This is an
7 area, like Ray said, that's a little newer to us,
8 and we are embracing it, and that is our intention,
9 to work with you collectively, so that the consumer
10 can benefit. So that we don't have the scare of the
11 month.

12 And thank you very much for coming.
13 Please, please get your comments in to us. You will
14 have ample opportunity to read this guidance
15 document over the next couple weeks. Get your
16 comments in to us. It's very, very important that
17 your voice be heard.

18 Camille, anything? Any final wrap-up.

19 CAMILLE: No, thank you so much.

20 MS. DENIKE: Thank you very much for
21 coming. The meeting is adjourned.

22 (Meeting concluded at 2:28 p.m.)

23 END OF RECORD

24

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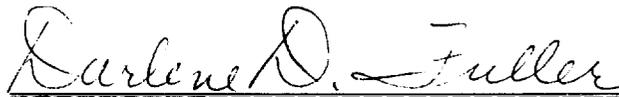
1 CERTIFICATE

2 STATE OF MICHIGAN)
3 COUNTY OF KENT) ss.

4 I, DARLENE D. FULLER, Certified
5 Shorthand Reporter and Notary Public, do hereby
6 certify that the foregoing meeting was held in my
7 presence at the time and place hereinbefore set
8 forth;

9 I FURTHER CERTIFY that this meeting was
10 recorded in shorthand, and thereafter transcribed by
11 me personally with the assistance of computer-aided
12 transcription, and that it is a true and accurate
13 transcription of my original shorthand notes.

14 IN WITNESS WHEREOF, I have hereunto set
15 my hand this 3rd day of December, 1997, in Reed
16 City, Michigan.

17
18 

19 Darlene D. Fuller, CSR-0929
20 Notary Public in and for the County of
21 Osceola, acting in the County of
22 Kent, State of Michigan
23 My commission expires 9-16-99.
24
25