

1 exploring the options for a national marketing order
2 that would include handlers and growers in this country
3 and beyond.

4 All of these are designed to provide for
5 mandatory adherence to the best practices that have been
6 developed by industry in close collaboration and concert
7 with academia and the regulatory community. And this
8 adherence would be overseen by state and federal
9 government authorities.

10 Just talking briefly about some of the new
11 specific GAP metrics, again, you know, the risk areas
12 have been known for sometime -- water, wildlife, soil
13 amendments, workers, et cetera. You've heard them
14 itemized several times today.

15 In the area of water, we are developing
16 specific best practices for the testing, the analysis,
17 the measurement, the evaluation of water sources and
18 distribution systems prior to and during production to
19 assure the safety of this critical input. We have put
20 forward specific numerical values for microbial
21 indicators that can be used to evaluate system
22 performance and input safety and protocols to further

1 evaluate and take action when those values are exceeded.

2 In the area of soil amendments we are doing
3 the same thing: Requirements for evaluating the safety
4 of soil amendments that contain composted or heat-
5 treated animal products have been established. The
6 requirements include a validation of the treatment
7 process that's in conjunction with soil amendments as
8 well as additional testing for pathogens and a time
9 interval prior to their application and the harvest of
10 the crop. These metrics are based on state standards
11 for composted material.

12 In the areas of animal intrusion and adjacent
13 land use we have also significantly stepped up what we
14 are asking the industry to do. And, basically, it's
15 performed preproduction, preharvest, and at-harvest
16 assessments of the risk associated from these potential
17 points of contamination to look for signs of intrusion,
18 to document everything, and make it available in a form
19 that can be accessible to investigators and inspectors
20 should an outbreak occur or should the inspectors and
21 verification system access those when they need to
22 access those for compliance purposes within the

1 marketing agreement. So the produce industry, you know,
2 continues to kind of lead in this area; and we continue
3 to serve as a catalyst for change and for improvement of
4 the current systems that we have in place.

5 I would say, I guess -- just going back for a
6 second about the marketing agreement -- the current best
7 practices that we have developed have been proposed and
8 a motion to accept them was made at the last leafy-
9 greens marketing agreement board meeting. The motion's
10 been tabled for a week while we work to finalize
11 proposals for full-fledged inspection and verification
12 programs; and we also bring forward proposals for
13 training programs that can be implemented within the
14 industry to ramp up the knowledge base, if you will, on
15 the new metrics and best practices that's being
16 proposed.

17 So now on to, you know, some of the specific
18 questions in the Federal Register notice. FDA's first
19 issue asked about unit operations or stages in the
20 supply chain and the corresponding risk. That's been
21 talked a lot about today, but it's important to note
22 that unit operations or stages include production,

1 harvesting, and transportation from the field,
2 receiving, cooling, processing, transportation and
3 shipment, receiving and storage at other levels, food
4 service, preparation, retail display, and end-use. And
5 it does not take into account at that point, you know,
6 that list what happens prior to production or post
7 sales. So contamination can be introduced in any one of
8 these stages. The industry has attempted to focus on
9 those areas of the supply chain with the most risk to
10 the greatest amount of product and by extension the
11 greatest number of people may occur will be affected
12 [sic], so that continues to drive us to areas of
13 production, harvest, cooling, and processing. But we
14 can't overlook handling in both retail and food-service
15 operations because they can present significant
16 potential for risk as well.

17 How should current practices be changed to
18 reduce the risk of contamination? I think, absent the
19 proverbial silver bullet that ensures the safety of all
20 finished products for consumers, the industry will
21 strive to continue to develop standard operating
22 procedures and best practices that can minimize the

1 potential for contamination. We are focused on
2 prevention. We focus on steps that can be taken to
3 prevent the introduction, as opposed to trying to deal
4 with pathogens once they are in the system.

5 To do this, we are working on a multiple-
6 hurdle approach, some of which we have itemized in the
7 metrics there. And that's a similar approach to some
8 that are being used in other industries, such as the
9 beef industry, where there's been a successful reduction
10 in the incidence of foodborne illnesses associated with
11 those commodities. But every unit operation in the
12 supply chain does implement steps to prevent
13 introduction of contamination. In the production and
14 harvest environment those practices are developed from
15 guidance that's been formulated through industry,
16 academia, and government collaboration. But programs
17 are also in place in processing facilities up and down
18 the supply chain.

19 I think, you know, that we need to continue to
20 refine; we need to continue to review; we need to
21 continue to inform these programs based on research,
22 which is another thing that has been highlighted here

1 this morning and I'll talk about here in a second.

2 But our attention, again -- you know -- and I
3 guess the question -- the question in the Federal
4 Register notice about inputs, our focus has been on
5 inputs, including irrigation water, soil amendments,
6 wash water, sanitizers, et cetera, and the need to
7 sample these routinely in agricultural production
8 systems and beyond.

9 And in addition to this sampling, you know,
10 we're recommending, you know, that it be implemented
11 more frequently and, you know, consistently within the
12 entire supply chain looking for indicator organisms such
13 as generic E. coli and in some instances looking for
14 specific pathogens.

15 It's important to note that the federal
16 actions that are highlighted in Sections 1 B through 1-
17 E, you know, have placed a lot of emphasis and a lot of
18 responsibility on the industry for the development and
19 implementation of practices and procedures to reduce
20 risk. And we have responded, you know, with the good
21 agriculture practices, the commodity-specific
22 guidelines, et cetera. But the reliance on industry,

1 while appropriate and well placed, still, I guess,
2 brings the question, you know, of what else can FDA do
3 or others do.

4 And I think, you know, in that regard we
5 wanted to make a couple of recommendations. First, you
6 know, we appreciate the collaborative work and
7 relationship that we've had with the regulatory
8 community in the past and we believe that we need to
9 sustain this, particularly in the prospect of trying to
10 analyze some of those more recent events and rank
11 suspected points of contamination for potential as a
12 source. Attribution, you know, and source information
13 is going to be one of the things that we need to
14 continue to strive to define if we are going to be able
15 to, you know, enhance the best practices that are
16 engaged and employed by the industry. We also believe
17 that resources need to be allocated to this -- resources
18 that can help underwrite research that can leverage
19 industry money to help fund research and training and
20 other things that need to go hand in hand with the
21 development and improvement of metrics.

22 There's been a lot of discussion about

1 traceback. And industry is, you know, very interested
2 in this. We've heard a lot of discussions in the past
3 about traceback systems not being adequate to facilitate
4 quick response, but every time we've asked we have not
5 been able, you know, to have any real feedback on here's
6 what we would like to see the industry do better.

7 Rapid traceback is in everybody's best
8 interest. It allows investigators and companies to
9 pinpoint and put definitive limits on the amount of
10 product in question right away. So, you know, we're
11 strongly in favor of trying to bring forward some
12 traceback standardization, if you will -- at a minimum
13 documentation that can be maintained that would allow
14 investigators to trace back from the retail outlet to
15 the suppliers, identify their location, the product and
16 number of cases ordered and delivered, to trace that
17 back to individual packages which contain information
18 that would indicate dates, shifts, lines within a
19 processing facility, and the date the product was
20 received at the processor.

21 I think I'm probably cutting into Dr. Harris's
22 time here, so maybe in kind of conclusion we're going to

1 submit written remarks or written comments on all of the
2 Federal Register questions. I would just say, you know,
3 that we are operating on a common goal -- protecting
4 public health -- doing all that we can to reduce the
5 number of outbreaks of foodborne illness associated with
6 fresh fruits and vegetables. Western Growers and other
7 industry partners are committed to that, you know.

8 We caution that because this is not
9 necessarily a sanitary environment that we will not be
10 in a position in the near-term future to guarantee that
11 these outbreaks will not occur but we are in a position
12 to commit to move the industry forward more rapidly than
13 any other proposed construct and to continue to serve as
14 a catalyst for enhancements to the fresh produce food-
15 safety systems.

16 MR. LANDA: Thank you, Mr. Giclas. If you
17 don't mind, if you would stay. We'll ask questions and
18 then we'll hear from Dr. Harris. That will help me
19 limit the questions to the panel.

20 Dr. Acheson.

21 DR. ACHESON: Thank you. Let me give my
22 question quickly.

1 You mentioned that the proposed market order
2 that you are working on was going to come ninety percent
3 by volume -- I think that's what you said -- of the
4 industry. What's your perspective on what's going on
5 with the other ten percent?

6 MR. GICLAS: Well, our perspective is that
7 we'll be able to shift that other ten percent in through
8 the marketing order. Our perspective is that we need to
9 capture that other ten percent, but, you know, our
10 movement, again, is kind of a tiered approach based on
11 what we can do most rapidly. But the ultimate, you
12 know, goal, if you will, is to try to move this to a
13 mandatory construct for all suppliers and for all
14 handlers.

15 MR. LANDA: Mr. Roh.

16 MR. ROH: Thank you, Hank, for presenting
17 today. We really appreciate it.

18 Did I understand you correctly to assume that
19 Western Growers does support some sort of enhanced
20 recordkeeping requirement, be it through advanced
21 guidelines, market order, or, if necessary, state or
22 federal regulations?

1 MR. GICLAS: Absolutely. I mean we are in the
2 process of developing, if you will, the details of our
3 proposed vision for the verification system. The
4 verification system obviously will be ultimately
5 implemented by CDFA and USDA inspectors in association
6 with the marketing agreement, but throughout the
7 metrics, throughout the new best practices and the
8 production and harvest end of the supply chain there are
9 numerous requirements for records and documents to be
10 maintained at either the handler or grower location. And
11 we are writing those in up-front as a means of trying to
12 facilitate, number one, the gathering of additional
13 information about some of the key inputs and things like
14 that; and, number two, to facilitate inquiries that may
15 come either from the inspectors charged with verifying
16 or tracebacks that may occur if there is, God forbid, an
17 event.

18 MR. LANDA: Dr. Buchanan.

19 DR. BUCHANAN: Hank, long experience with
20 working in other aspects of the food industry has
21 indicated that often problems are aggravated by poor
22 design of equipment and processors.

1 And has the industry taken any look at all at
2 the equipment it currently uses at the farm level and at
3 some of the practices that they have there to try to
4 tease apart what are some of the areas that can be
5 improved? For example, I look at a spinach-harvesting
6 machine and say that would be a great way of
7 contaminating a product. Is there any evaluation of
8 that type of technology to find better ways of doing it?

9 MR. GICLAS: There is absolutely a constant
10 look at both -- I mean on the part of industry -- by
11 both companies who are individually manufacturing and
12 building some of these and trying to improve them.
13 There's also, as Dr. Farrar said earlier, there's a very
14 comprehensive research agenda that has been proposed.
15 And some of those items are being looked at.

16 And the focus of our best practices and
17 metrics so far have not been necessarily on replacing,
18 you know, existing equipment or existing schemes, if you
19 will, within the industry but rather, you know, how do
20 we work to prevent contamination in the systems that are
21 currently in the field.

22 The second part of this is a second-tiered

1 question; that is, I think it's a research question and
2 baited question, et cetera.

3 I would also say that we haven't had a lot of
4 feedback, although we do continually look at these
5 things, that these are necessarily the highest orders of
6 risk and the highest orders of focus for us at the
7 moment.

8 MR. LANDA: Ms. Bohm.

9 MS. BOHM: You mentioned and I wasn't -- I
10 wasn't quite clear on what -- where along the way this
11 will occur. You mentioned that state and federal
12 inspectors would be able to enforce or verify adherence
13 with particular something. And my question was I
14 understand that this is -- currently, anyway -- a
15 voluntary approach and how will an inspector at any
16 level be able to enforce something that's not a law?

17 MR. GICLAS: You know, we don't like the use
18 of the term "voluntary." It's not a voluntary
19 construct. It is a mandatory construct for those
20 individuals who sign on to the marketing agreement. So
21 anybody who signs into the marketing agreement today --
22 and we have fifty-three out of seventy-nine handlers

1 subscribing in California today, representing
2 approximately ninety percent of the volume of commercial
3 product.

4 But for all of those people who sign in, they
5 are bound by contract to only source product from
6 growers who are implementing the best practices that
7 have been accepted, if you will, by this marketing
8 agreement board. Those best practices are the next --
9 they're almost the third generation, if you will, of
10 commodity-specific guidance put forward by the industry.
11 And they contain a lot more specifics, if you will, in
12 terms of the numerical values that can be measured
13 against, et cetera. That whole system will then be, you
14 know, verified, if you will, by state and federal
15 inspectors who are employed by the marketing agreement
16 board under separate contract and go out and observe,
17 you know, what the handlers are doing, do their sourcing
18 (inaudible) of what's going in the fields, et cetera. So
19 that verification system right now, what they look at,
20 when, frequency -- those types of things is in the
21 developmental process. But the marketing agreement
22 really officially kicks off April 1, 2007, so we're

1 pushing forward to have that done and ready.

2 MR. LANDA: Ms. McGarry.

3 MS. MCGARRY: You mentioned the verification
4 component to the marketing agreement and in some of the
5 outbreak investigations, there have been audits done of
6 the growers and that have received high scores. What in
7 the marketing agreement is addressed to try to ensure
8 the training and qualifications of those who are
9 conducting audits? And is it strictly a government
10 auditing or is it a private/government? Can you talk a
11 little bit more about that.

12 MR. GICLAS: Yeah, at this particular point in
13 time, the vision for this verification system and for
14 the inspectors that will be, you know, engaged under the
15 verification system is for it to be a government
16 construct. In other words, it would be a USDA or a CDEA
17 employee operating under USDA authority that would go
18 out and do the verification.

19 You will have to talk with CDEA specifically
20 about the level of training that those particular
21 auditors are going through, but it is, you know, a
22 fairly significant series of, you know, training that

1 positions them to be able to pick this program up and
2 run with it. And they do these types of verifications
3 and audits throughout the country in different areas so
4 -- and in different commodities. And at some point in
5 time they may be able to certify third-party inspectors
6 or others. But, again, for the first year, for the
7 foreseeable future, it's going to be a state or federal
8 inspector.

9 MR. LANDA: Ms. Bohm.

10 MS. BOHM: Can you explain what you foresee as
11 the driving factor or factors that will encourage those
12 producers who haven't signed on yet to sign on and
13 therefore protect all consumers, not just the ones of
14 the consumers who are purchasing product of the
15 producers who have signed up?

16 MR. GICLAS: Well, in terms of trying to
17 provide incentives for individuals to sign on we have
18 had separate conversations with buyers and others to try
19 to encourage them to source their product from
20 individuals who are subscribed to the marketing
21 agreement. But I don't think that ultimately we will be
22 able to incentivize, for lack of a better term,

1 everybody to get into the program, which is why we're
2 moving to the marketing order, which upon a super-
3 majority vote would make it a mandatory construct for
4 everybody.

5 MR. LANDA: I just have one question. What
6 kind of micro testing are growers doing now and what
7 should they be doing?

8 MR. GICLAS: Well, you know, I think growers
9 now today, again, are looking at the integrity, the
10 safety, the quality of their inputs. I think what we
11 are doing -- one of the -- I guess one of the challenges
12 of generic guidance is we don't tell people exactly what
13 to look for, exactly how often to look for it, exactly
14 where to take the samples -- you know, those types of
15 things. So what we are trying to do is come forward
16 with a lot more solid and specific information to drive
17 and to sort of standardize -- here's the best practice,
18 if you will, in the industry. So all of the things that
19 we are talking about today with currently sampled, you
20 know, by growers in the field at some level or another.

21 Are they all operating on the same level? I
22 couldn't answer that.

1 MR. LANDA: Ms. McGarry, last question. And
2 one question, no two-parters.

3 MS. MCGARRY: There has been a lot of talk
4 about the testing component of the marketing agreement;
5 and while testing (inaudible) can be a very useful tool
6 and give you a snapshot, what's the balance in the
7 program of the metrics between testing and preventive
8 means and environmental -- kind of comprehensive
9 assessment of what's going on (inaudible).

10 MR. GICLAS: Everything that is employed in
11 terms of testing is really employed as part of a
12 surveillance or monitoring program more than anything
13 else.

14 If you just look at water, for example, one of
15 the things that we're asking everybody to do is go back
16 and do a risk assessment associated with their sources,
17 their distribution systems, the environment that's
18 surrounding those areas and look and identify the
19 potential points of risk that may be associated with
20 that system in that environment; to address those points
21 of risk; and then to use sampling data, et cetera, to
22 sort of monitor the integrity and performance of your

1 system over time. We're carrying that same rationale
2 forward with soil amendments and with adjacent land use
3 and every else. So it's not that we're trying to test
4 our way to safety, if you will. We're trying to put the
5 entire package forward as this multiple-tier approach
6 that will reduce risk when all of the factors are
7 combined.

8 MR. LANDA: Thank you, Mr. Giclas.

9 Our next speaker is Dr. Linda J. Harris, who's
10 associate director of research with Western Institute
11 for Safety and Security. She's with the Department of
12 Food Science and Technology at U.C. Davis and provides
13 statewide expertise on food microbiology to producers,
14 processors, retailers, and consumers.

15 DR. HARRIS: Well, thank you for inviting me
16 to give a presentation today.

17 Many people have already mentioned the need
18 for further research in this area; and the way I look at
19 my presentation is to couple both what is the state of
20 the science and what are some ideas for further
21 research. It was pretty challenging. There's been
22 research done in multiple disciplines in this area for

1 probably over sixty years. Most of the research,
2 however, has been within the last decade, as we
3 increasingly recognize the association with foodborne
4 illness and fresh produce.

5 I want to say that in looking at the overall
6 research that has been done, a lot of what you might
7 consider the low-hanging fruit -- the easy stuff -- has
8 been done. There's some very targeted research that is
9 left to do. But I think that in moving forward some of
10 the questions that are still remaining are big
11 multidisciplinary types of questions that are going to
12 take teams of researchers to try and solve. And I just
13 want to make that statement up front.

14 One of the challenges that I see to even
15 beginning to collect data when looking at food safety of
16 produce is just the diverse selection of produce that's
17 available in a typical U.S. grocery store -- anywhere
18 from three hundred to three hundred and fifty produce
19 items. Almost all of it is highly perishable. That
20 makes it a challenge to source product, to do laboratory
21 studies. Even if we narrow it down to the three or the
22 five or the seven top contributors associated with

1 foodborne illness, we are still talking about multiple
2 different items. And each of these types of crops --
3 melons or leafy greens, tomatoes -- the way in which
4 they are produced, harvested, and their post-harvesting
5 handling system differ. And they differ not only among
6 the produce types but within and among regions in the
7 U.S. and within and among countries. And so actually
8 the risks that we need to look at may be different
9 whether it's a tomato grown in California or a tomato
10 grown in Maryland. And I think that those are some of
11 the challenges that have contributed to some of these
12 issues.

13 In addition, you see varying lists of multiple
14 pathogens. We've heard that Salmonella and E. coli
15 O157:H7 are near the top of the list, but there are
16 others. And each one of them has either different major
17 sources, different groups of contamination.

18 Another factor when looking at naturally
19 contaminated product, because you can learn a lot from a
20 naturally contaminated product, is the state of the
21 organism, the levels that are there compared to
22 organisms that you are inoculating in the laboratory.

1 But with produce -- and it's a very fortunate thing --
2 in general, we accept the fact that overall there's a
3 low level of contamination of these products. Otherwise,
4 we would see significantly more illness. So the percent
5 of positive units are very low. And that makes it a
6 challenge to do surveys in a statistically valid manner.
7 We don't have virtually any data on what the numbers of
8 the pathogen might be on a naturally contaminated
9 produce item, but we do believe that those numbers are
10 likely to be very low; and that also makes it
11 challenging.

12 We also don't have very good information on a
13 naturally contaminated field or lot. How likely is that
14 contamination to be uniform? And I think most
15 scientists would agree that it's unlikely, given the
16 variability of a field and the variability in the way we
17 believe that produce is contaminated. So low-level
18 contamination, low numbers per positive unit, and uneven
19 distribution make statistically valid studies of
20 naturally contaminated products difficult.

21 Now, if we look at any of the pathogens that
22 have been listed and we ask the question how do they

1 survive in the environment, the data that has been
2 generated by multiple researchers over the last couple
3 of decades certainly indicate that these organisms are
4 more robust in the environment than traditionally
5 considered. So instead of surviving for days they
6 survive potentially under certain circumstances for
7 weeks and perhaps months in the environment. It's less
8 clear if they are able to also exist in stable
9 multiplying populations in the environment in the
10 absence of a host. This idea was brought up maybe
11 thirty years ago. There's been very little research
12 since then, but most people think that you get
13 contamination and then prolonged survival, but I think
14 that in certain circumstances the ability for these
15 organisms to multiply in the environment is possible;
16 and there's evidence of generic E. coli multiplying in
17 tropical environments and stable populations.

18 So when we look at them, one of the primary
19 reservoirs for these pathogens -- we talked about the
20 animal and the human factor. We also have to look at
21 the environment. If organisms are surviving for longer
22 periods of time in the environment then the movement

1 through the environment is important. And depending on
2 where the organism is coming from -- what is the primary
3 route of contamination? Is that direct contact? Is it
4 water? Is it dust? Is it aerosols? And I would think
5 that in different circumstances any one of those things
6 could be a factor?

7 Obviously, we are working with human
8 pathogens, so generating data on how these organisms
9 survive in the field has been a challenge, to say the
10 least. You can't as a researcher, no matter how much
11 you might want to, you can't go out in the field and
12 start spraying around Salmonella and E. coli to identify
13 exactly what happens to these organisms in a field. But
14 I think we have generated some information on behavior
15 in greenhouse plants. I think there's more information
16 we need to understand about the specific environmental
17 factors -- such as humidity and UV index, moisture --
18 that will influence pathogens; and I think we can do
19 more work in this area in the laboratory that is
20 targeted to factors that also occur in the field.

21 In addition, we've also heard about the
22 connection between Salmonella and tomatoes and E. coli

1 0157:H7 and lettuce and leafy greens; and I think that
2 there are some evidence beginning to be published that
3 there's generous species or even strains that may be
4 adapted to unique environments presented by these
5 various produce items. I think that this is an area of
6 further research. If this proves out to be a case we
7 need to understand better the molecular level why these
8 abilities exist; and then that may ultimately lead to
9 ways in which to control the proliferation.

10 Now, Hank already mentioned -- everybody
11 mentioned -- good agricultural practices as a means of
12 reducing risk contamination. And I think that's where
13 our focus is. And people have mentioned water; soil
14 amendments, or manure; workers; and wildlife. I put
15 adjacent land use, because domestic animals could come
16 into play with that as well.

17 And even though we have metrics I think
18 everyone would agree that it's a place to start, but
19 there's certainly room for adding some more science to
20 some of those metrics. And does an individual evaluate
21 the risk of a single animal in a field? How do you
22 continually monitor? Are we using the right monitoring

1 tools? And how do you ultimately manage the risk or set
2 up corrective actions where risk is identified?

3 So even though we do have composting
4 guidelines that have been developed, I think there is
5 still work to be done in this area. How to best
6 validate a composting operation? How to best monitor?
7 How to best verify? And answering questions on what
8 happens when the contamination of composed materials
9 occurs, how significant that is in leading to the
10 overall risk.

11 Now, I'm going to throw up this slide on
12 preharvest internalization of pathogens only because
13 everybody brings it up and I just want to deal with it.
14 The state of the science is that, yes, under laboratory
15 condition under certain circumstances with certain
16 organisms and certain plants it has been demonstrated
17 that pathogens can be taken up by either the root system
18 or, in the case of inoculated flowers, sometimes into
19 their mature fruit. But I think that the missing link
20 has been how likely are the conditions that have been
21 used under laboratory studies to occur in the field and
22 so is that data transferrable into the field?

1 There's another several factors, including the
2 microbe and the plant itself. But I think, also, we all
3 have to remember that, even if we say that this is
4 possible to happen in the field, I think we have to look
5 at the picture and ask the question what does it really
6 contribute to the overall risk of foodborne illness. And
7 I think that, still, external contamination -- roots of
8 contamination -- are probably always going to be more
9 significant than some type of internalization.

10 Now, washing produce does not eliminate the
11 problem; and if it did we probably wouldn't be here
12 today. There's been a tremendous amount of data
13 generated on a tremendous number of antibiotic
14 microbials that can be used in wash water. And
15 antimicrobials effectively used in wash water are
16 excellent means of reducing cross-contamination of
17 produce; and I would argue that's their number-one use
18 in packing houses and in processing facilities. They
19 can reduce populations of microorganisms externally
20 applied.

21 And we know that the reduction is highly
22 variable. It's easier to reduce microorganisms from

1 unblemished and undamaged and unwaxed skin, especially
2 when you can apply some sort of physical force. But as
3 soon as you start looking at blemishes or damages or
4 injuries or skin scars, the difficulty goes up; and when
5 you have complex or delicate surfaces where physical
6 force is difficult then again you have a reduced
7 efficacy.

8 Despite the fact that significant research has
9 already gone on in this area, I think there is still
10 hope for additional -- perhaps better -- methods for
11 certain types of fruits and vegetables. And it's
12 already been mentioned that ideally you would have a
13 kill step that was -- that could be validated and
14 monitored and reliably implemented.

15 Now, this is a slide talking about post-
16 harvest infiltration of pathogens. And this is where I
17 would think this is one of the research areas that we
18 know that this can occur. And it's been demonstrated
19 for a number of fruits and vegetables. We know that
20 temperature and pressure differential are important --
21 water deficit, depth of water. But this can absolutely
22 be controlled by maintaining water quality. So this is

1 one of the areas that, you know, you don't need a lot of
2 research to put something into action, which is already
3 in action, I would argue.

4 I think that are some questions still
5 remaining in this area; and that is, in the absence of
6 water, can you still have infiltration at cut surfaces
7 or wounds or during vacuum cooling? And what happens to
8 the organism once it's internalized? How does it
9 behave? Does it die? Does it multiply in certain
10 circumstances?

11 And speaking of survival and multiplying, this
12 is an area, also, that is well studied, basically, on
13 intact fruits and vegetables with no wounding. Survival
14 is variable depending on the type, depending on the
15 available of moisture so that a high-humidity
16 environment, where there's usually free moisture on the
17 fruit or vegetable and then permissible temperatures
18 also influence that. And in some intact fruits and
19 vegetables, researchers have demonstrated multiplication
20 on some intact fruits given the right conditions of
21 moisture and temperature.

22 Once you cut or wound a fruit or vegetable,

1 pathogens have been shown to be attracted to the cut
2 surfaces. Survival and growth potential increases and
3 even acidic products, such as chopped tomatoes have been
4 demonstrated under certain circumstances to support the
5 growth of pathogens. Certainly, growth in nonacidic
6 products like melons has been clearly demonstrated.

7 I'm going to finish up with just a couple of
8 comments on microbiological methods, because the data
9 that you generate and the way you interpret your results
10 is highly influenced by the method that you choose and
11 the design of the study. And I would say -- and I think
12 a lot of people in the room would agree with me -- that
13 there have been almost as many methods used in research
14 as there have been studies done and that microbiologists
15 unfortunately don't like to use other people's methods
16 very often; and I think that actually has been
17 detrimental in some ways to moving things forward.

18 I think we haven't taken enough consideration
19 of the state of pathogens at the time that we do
20 laboratory studies and inoculate. We know that
21 environmental and naturally contaminated fruits and
22 vegetables are likely to be contaminated by stress

1 itself; and I think we need to look more closely at that
2 to ensure that what our data is saying is relevant.

3 Inoculation method has been studied extensively, but I
4 think there's still not necessarily a consensus in this;
5 and then recovery methods will influence whether or not
6 you're able to identify all the viable microorganisms
7 remaining.

8 So I would strongly suggest that the microbial
9 research community look at greater evaluation,
10 validation, and justification of the methods that they
11 are using; and I think more laboratory studies should
12 attempt to mimic approximate and realistic environmental
13 conditions. I also think that there might be a need for
14 better coordination and agreement or encouragement of
15 researchers to agree on standards methods and that
16 methods should be shared when somebody has a new method
17 that is working better than the old; and development of
18 approved methods in sampling strategies. And I stress
19 the sampling strategies for interpretation of data and
20 for finding and recovery of pathogens from environmental
21 samples is also really critical.

22 With that, I'll --

1 MR. LANDA: Thank you, Dr. Harris.

2 The next speaker also has to leave fairly
3 early this afternoon, so I think we're going to have her
4 up here. And then, time permitting, with your schedule
5 and hers, we'll ask you back for questions.

6 Our next speaker is Lisa Odabashian, who's the
7 West Coast director of Consumers Union, which is a
8 nonprofit publisher of Consumer Reports. She's an
9 expert on food-safety issues.

10 MS. ODABASHIAN: Good morning. My name is
11 Elisa Odabashian, as you've heard. I am the West Coast
12 director of Consumers Union, the nonprofit publisher of
13 Consumer Reports magazine, with four million
14 subscribers, and Consumer Reports Online, with more than
15 2.5 million subscribers.

16 I appreciate today's opportunity to
17 participate in this public conversation with the FDA
18 about the safety of fresh produce. You've heard today
19 from a number of scientific experts from government and
20 industry about all that has been done and is being done
21 and will be done, hopefully, about the safety -- to
22 ensure the safety of fresh fruits and vegetables, much

1 of which is grown in California.

2 I've been asked here today to give the
3 consumer perspective. That perspective is currently
4 worth a hundred million dollars. It's a hundred million
5 dollars in lost revenue to the California leafy-green
6 industry in just about five months, because last
7 September more than two hundred unlucky consumers across
8 twenty-six states ate spinach contaminated by a
9 particularly virulent form of E. coli that killed
10 between three to five, hospitalized more than a hundred,
11 and sickened another one hundred.

12 The spinach disaster was quickly followed by a
13 Salmonella outbreak from contaminated tomatoes served
14 from a restaurant which sickened one hundred eighty-
15 three people in twenty-one states. On the heels of this
16 came another E. coli outbreak from shredded lettuce at
17 Taco Bell and Taco John restaurants that sickened one
18 hundred fifty-two people.

19 A national survey released by Rutgers
20 University's Food Policy Institute last month suggests
21 that last September spinach recall could have lasting
22 effects on consumers' consumption of spinach and other

1 vegetables. The survey showed about one in five people
2 who were aware of the recall also stopped eating other
3 bagged produce. More than seventy-five percent of the
4 responders with spinach in their home threw it out
5 during the recall; and seven percent threw out fresh
6 produce other than spinach. More than half of the
7 people who typically ate spinach prior to the recall had
8 not returned to eating it when the survey was taken
9 months later.

10 At this moment, all across America, the
11 consumer perspective is one of deep disappointment in
12 government agencies, both at federal and state levels,
13 that have failed to safeguard the food supply -- deep
14 distrust in the leafy-green industry that is responsible
15 for nearly two dozen foodborne illness outbreaks in the
16 last ten years and confusion about whether fresh fruits
17 and vegetables are indeed the most healthful foods to
18 eat or whether they're potentially deadly.

19 In 1997, President Clinton, as part of the
20 Produce Safety Initiative, assured Americans that fresh
21 fruits and vegetables met the highest standards of
22 safety, directed FDA to issue voluntary industry

1 guidelines outlining good agricultural and management
2 practices for growers, processors, and distributors.
3 Ironically, from almost the minute those voluntary
4 guidelines were issued in 1998, the public has endured
5 recall after recall after recall of produce containing
6 microbial contamination. Clearly, the FDA's voluntary
7 approach to regulation of fresh produce has utterly
8 failed to make it safer.

9 There's only one way to ensure that fresh
10 fruits and vegetables that reach the marketplace are
11 safe -- only one way to rebuild consumer trust. FDA or
12 the California Department of Health Services, separately
13 or in conjunction, must assume the authority and be
14 given the staff to effectively mandate GAPs for every
15 farm and HACCP programs for every processor, including
16 thorough and regular inspection programs, effective
17 traceback programs, third-party audits, and rigorous
18 enforcement of standards. The leafy-green industry in
19 particular has brought dangerous products to market too
20 many times for consumers to believe that it will
21 suddenly meet voluntary safety standards. For many
22 consumers, it's simply safer to stop buying leafy-green

1 products altogether, healthy notwithstanding.

2 In California, the California Department of
3 Food and Agriculture -- CDFA -- in partnership with the
4 leafy-green industry is furiously pushing forward a
5 marketing agreement, of all things, to development
6 voluntary best practices standards. This is being done
7 behind closed doors without any public input.

8 Furthermore, the CDFA is allowing the oversight board to
9 be made up almost exclusively of the leafy-green
10 industry, some of which have been accused of marketing
11 contaminated products. CDFA has admitted that they will
12 accept whatever best practices the very industry that
13 brought us spinach contaminated by E. coli comes up
14 with. This is a serious abdication of government's duty
15 to certify the food supply and protect the public.

16 Industry self-regulation seldom protects consumers and
17 often provides industry with cover when contamination
18 occurs. Simply put, if the leafy-green industry ever
19 hopes to regain consumer trust, it must be regulated by
20 an authority other than itself.

21 Now, by its very nature, a voluntary program
22 of safety standards does not account for the bad actors

1 and does not ensure that all products that come to
2 market are safe. Nor do voluntary standards create an
3 incentive for everyone to comply, particularly when
4 meeting safety standards cost money. If not all
5 producers and processors are subject to the same
6 standards the door remains open for contaminated produce
7 to reach consumers, with all the attendant negative
8 public health effects, publicity, and economic impact
9 that that incurs.

10 Another bad idea that has come out of this
11 California industry-driven marketing agreement is the
12 use of a certification mark to convey to consumers that
13 leafy-green products from participating farms and
14 processors in California are subject to best practices.
15 This approach turns safety into value-added in the
16 marketplace. The safety of the food we buy is a
17 fundamental expectation of consumers. And government
18 must ensure it. Safety should not something that is
19 used as a marketing tool when it comes to food. It
20 should not be something that consumers must search out
21 and possibly pay extra for, leaving poor consumers at
22 risk. All of our food should be safe.

1 Now is the time for FDA to do everything in
2 its power, including seizing adulterated products, as
3 authorized by Section 402 of the Federal Drug and
4 Cosmetics Act and established HACCP programs on farms
5 and as authorized by Section 361 of the Public Health
6 Services Act to ensure the safety of produce.

7 Further, FDA must expand its power by
8 demanding that Congress give it more money and staff to
9 effectively enforce mandatory authority over this
10 industry. Again, the voluntary approach to regulating
11 this industry simply has not worked and will continue to
12 endanger consumers with contaminated products.

13 A recent Associated Press analysis of the
14 federal records found that in 2006 FDA conducted just
15 half the inspections of U.S. food manufacturing
16 facilities that it did three years earlier in 2003. And
17 it conducted seventy-five percent fewer safety tests of
18 U.S. produced food in 2006 that it did in 2003.

19 Last May former FDA official William Hubbard
20 published an opinion piece in the Washington Post in
21 which he explained that for some years now the FDA's
22 budget has remained essentially flat while major new

1 responsibilities have been piled on, resulting in a
2 serious weakening of the agency. Mr. Hubbard wrote that
3 FDA food inspections dropped from fifty thousand in 1972
4 to about five thousand in 2006. That is a ninety-
5 percent reduction. And that U.S. food processors are
6 inspected on average about every ten years. Every ten
7 years. And that the chance of a food product from
8 overseas being inspected is in his words infinitesimal.
9 Clearly, FDA must demand considerably more resources for
10 food-safety inspectors and Congress must appropriate the
11 necessary funds immediately to sure the safety of the
12 food supply.

13 The FDA's voluntary industry guidelines
14 published last week states that -- and I quote --
15 prevention of microbial contamination at all steps in
16 the farm to table continuum is preferable to treatment
17 to eliminate contamination after it has occurred, end
18 quote.

19 Now, consumers representing the table side of
20 that continuum could not agree more. But prevention of
21 microbial contamination in fresh-cut fruits and
22 vegetables requires mandatory regulation that is

1 enforced by a government watchdog that does not have as
2 parts of its charge the promotion of the industry it
3 regulates.

4 Some essential components of the regulations
5 should be GAPs for all farms; HACCP programs for all
6 processors; written good safety plans showing how
7 producers will comply with GAPs; third-party audits;
8 traceback systems that include package identifiers so
9 that each item can be traced all the way back to the
10 field in which it originated; FDA inspections at least
11 yearly, made possible by substantially increased funding
12 by Congress; and, finally, FDA enforcement that has
13 teeth.

14 The FDA's guidelines fall well short of
15 industry oversight. They state, and I quote, FDA
16 guidance documents do not establish legally enforceable
17 responsibilities. Instead, they describe the agency's
18 current thinking on a topic and should be viewed only as
19 recommendations. The use of the word "should" in agency
20 guidance means that something is suggested or
21 recommended but not required.

22 I leave you today with a couple of one-

1 hundred-million-dollar questions from the consumer
2 perspective. First, why is the FDA only suggesting and
3 recommending safe practices for the fresh-produce
4 industry and not requiring them despite numerous
5 incidents of contaminated fresh-cut produce reaching the
6 marketplace and harming, even killing, consumers? And,
7 finally, how many more deadly outbreaks must there be
8 before FDA's "should" becomes a must. And their
9 suggestions recommendations and current thinking become
10 rigorous mandatory oversight by a credible government
11 watchdog that is well-funded and adamant about
12 protecting the food supply and public health? Consumers
13 are sitting on their pocketbooks waiting for the
14 answers.

15 Thank you.

16 MR. LANDA: Questions? Dr. Acheson.

17 DR. ACHESON: Thank you for your comments. We
18 appreciate it.

19 One of the points that you bring out is the
20 dilemma that consumers are facing in terms of the health
21 benefits of fresh produce versus the potential risks.
22 And essentially what that comes down to in my mind --

1 and I'm interested in your opinion -- is a relevant-risk
2 argument. Given as we have heard that reducing the risk
3 of fresh produce to zero is essentially not going to
4 happen in our lifetime, we will always be faced with a
5 relative-risk message. How, from your perspective, do
6 you see that best communicated to the consumers?

7 MS. ODABASHIAN: Well, I think consumers
8 understand that these products are grown in the outside
9 external environment; and things happen in the external
10 environment. But I think that we can expect that
11 contamination will be caught before it gets to the
12 marketplace. We understand that contamination will
13 occur, but consumers have right to expect that it will
14 be caught before it gets to the marketplace. And to do
15 that you need to put in a lot of steps, a lot of
16 tracebacks, a lot of inspections, a lot of rigorous
17 safety testing.

18 With regard to the message given to the
19 consumers, this has been one of the most difficult
20 messages to convey to consumers, because on one side
21 we're telling them that you can't stop eating vegetables
22 and fruits. It's the most important thing that you eat

1 for a healthy life. On the other side we have outbreak
2 after outbreak and people are calling us hand over foot,
3 writing our Web site, contacting us over and over
4 saying, Well, what do we do here?

5 And, you know, if it were -- with a lot of
6 other food issues like, for instance, bovine growth
7 hormone in milk, if consumers don't want that, we say,
8 Well, you can go and buy a product that says "not
9 produced with bovine growth hormone." You can buy
10 organic. If people want to avoid mad cow disease, if
11 they really are, you know, aimed -- you know, if they
12 really don't want mad cow disease, they can buy grass-
13 fed beef, they can -- not buy beef that has nervous-
14 system tissue in it. There are things that they can do
15 to safeguard themselves from such horrors. But with
16 this one we are left not being able to tell them
17 anything. Because in essence it's a bit of a crap shoot
18 when you go to the grocery store and you buy a head of
19 lettuce; and you just can't know. You can't know where
20 it came from, because it's not, you know, it doesn't
21 have a label on it. So consumers are really sitting
22 ducks around this one. And they really need

1 governmental intervention. They need it rigorous and
2 they need it mandatory.

3 MR. LANDA: Ms. Bohm.

4 MS. BOHM: You mentioned -- and you said other
5 speakers have as well -- you've mentioned the need for
6 increased oversight and increased number of inspectors
7 and all kinds of things that mean an increased budget
8 for that particular program. Do you believe consumers
9 are willing to pay the increased costs that this will be
10 generated not only by the government oversight but by
11 the required changes that would occur at the industry
12 level as they increase their testing and increase their
13 whatever?

14 MS. ODABASHIAN: Absolutely, I believe it. I
15 believe that consumers are willing to pay more if they
16 are guaranteed a safe product. But what we don't like
17 is when some products in the marketplace are considered
18 safe because they have a certification mark and they're
19 probably more expensive, possibly; and others are not
20 safe because they don't have the certification mark. We
21 want to make sure that there's a standard of safety for
22 everything in the marketplace. But I do believe that

1 they would be willing to pay for that, yes. And I
2 believe Congress should give you more.

3 MR. LANDA: Dr. Buchanan.

4 DR. BUCHANAN: I'll going to ask a question
5 that is in some way rhetorical, but I would appreciate
6 your insight into this. One of the things that FDA is
7 faced with on a continuing basis is -- we will call them
8 opposing activity. We have the need to establish
9 rigorous safety programs. We also then must deal with
10 issues like the organic rule that comes out in
11 pertaining in terms of certain technologies, at least in
12 the view of consumers.

13 We have the need to be able in many ways
14 isolate food production area, but we have consumers
15 moving their suburbs into the rural areas so that we
16 interface two environments that should not likely be put
17 together.

18 We have concerns about the environment and
19 fostering wildlife habitat. At the same time we know
20 that food -- production areas -- there's a potential
21 area of contamination.

22 Do you have any insight on how we bring these

1 issues before the consumer and articulate the trade-off
2 that take place when you deal with these opposing risks
3 that we're facing.

4 MS. ODABASHIAN: I would say that,
5 unfortunately, the only way consumers learn about FDA is
6 when they get sick from food or they read in the
7 newspaper that a product has been recalled and one
8 hundred fifty-eight people have been sicken across
9 twenty-six states.

10 That's the only time most people even think
11 about the FDA. And I realize you have lots to do, but
12 protecting the food supply should be goal number-one;
13 and consumers believe that strongly. And most of them
14 don't realize that the safety standards for industry
15 producing food are not mandatory. Most of them believe
16 that there is a government body who is rigorously
17 overseeing the safety of the food that gets to market;
18 and when they learn that that's not the case there's a
19 lot of anger. We've experienced an enormous amount of
20 anger over the last six months from consumers whose
21 faith has been shattered by outbreak after outbreak
22 after outbreak on a product that they want to eat, they

1 should be eating. And we don't know want to tell them,
2 frankly.

3 MR. LANDA: Thank you very much.

4 Dr. Harris, if you can come back, please.

5 Questions for Dr. Harris? Ms. McGarry.

6 MS. MCGARRY: Dr. Harris, you mentioned water
7 quality and the effects of post-harvest cooling. Can
8 you talk a little bit -- or if you know -- a little of
9 the science on the role of turbidity on the water
10 quality in this connection?

11 DR. HARRIS: I think that that depends on the
12 microbial that's within the water and the turbidity. I
13 think it's your monitoring system to ensure that the
14 level of a microbial is there in this function. And I
15 can't say particularly. I'm sure that turbidity has
16 some impact on water quality.

17 MR. LANDA: Dr. Buchanan.

18 DR. BUCHANAN: Linda, you graciously agreed to
19 participate in a research priority-setting activity a
20 few weeks ago to get a consensus on what are the
21 priority areas that need to be dealt with. And I wonder
22 if you would reflect on that process and whether that

1 process should be used for a variety of other
2 commodities.

3 For the audience, I'm referring to an NHS
4 activity that took place with tomatoes; and there seems
5 to have been a very different approach to setting the
6 research agenda for tomatoes, which was done on much
7 more of a national level than there has been for leafy
8 greens, which has been primarily set based on
9 consideration of one region of the country.

10 Would you reflect on -- you've been involved
11 in both processes. Could you reflect on that?

12 DR. HARRIS: In fact, I was involved yesterday
13 in a process for strawberries, so I've had multiple
14 experiences.

15 I think that one of the reasons that the
16 research priorities were dealt with in California for
17 lettuce and leafy greens was because, as you've already
18 previously pointed out, this is where the problem was.
19 This is where it is. And, quite frankly, the majority
20 of the industry is here. And so by understanding how
21 the industry works here and what the issues are, what
22 the production practices are, I think we did have

1 national participation in that committee, including
2 yourself. As far as the tomato, you know primarily
3 tomatoes and Salmonella have been an East Coast issue --
4 Virginia, Maryland, and Florida. And, primarily, the
5 committee that met together was really focused on
6 experts from those regions. And I think with good
7 reason. I think it's good to get a broader perspective,
8 but I think the process is actually easier in setting
9 research priorities when you have a target to go after.

10 Yesterday we struggled a bit. Strawberries
11 have not been associated -- fresh strawberries have not
12 been associated with outbreaks, so setting a research
13 agenda there was a little bit more of a struggle on what
14 you put first and second and third. So with tomatoes
15 having Salmonella and leafy greens having E. coli, it's
16 been in some ways a little bit easier to identify what
17 you need to know to move toward.

18 I don't know if I answered your question.

19 MR. LANDA: Additional questions?

20 Dr. Buchanan.

21 DR. BUCHANAN: Totally separate one: The
22 produce industry is enamored with water with washing

1 things. It floats things. It moves things around in
2 streams of water, whereas, much of the rest of the food-
3 processing industry has learned that in terms of safety
4 you need to minimize water. Is there much in the way of
5 a research agenda finding alternate technologies that
6 start to reduce the produce industry's reliance on
7 water?

8 DR. HARRIS: Well, I think that was one of the
9 things that was brought up with tomatoes. One of the
10 reasons that water is used is because most fruits and
11 vegetables are exceptionally sensitive to bruising, so
12 water is used as a cushion and a way to gently move
13 product through a system. I think another example comes
14 where you look at melons that are harvested directly
15 into a box or heads of lettuce that are harvested. A
16 lot of products are harvested in complete absence of
17 water. Melons could be harvested either into a packing
18 house where water is added or in a field. I would agree
19 with you that although conceptually a wash step might
20 seem like a good idea, it also opens up opportunities
21 for contamination. So in the melon case if your melons
22 are not in need of a wash step that might be a better

1 approach. But, yes, I believe that people will be
2 looking at reduced water use.

3 MR. LANDA: Any other questions?

4 Thank you very much.

5 We'll break for lunch. Let's reconvene at
6 2:15.

7 (Lunch recess from 12:41 p.m. to 2:15 p.m.)

8 MR. LANDA: Our first speaker this afternoon
9 is Amy Green, who is a consumer safety officer in the
10 office of Food Safety in CFSAN. She is lead author of
11 the recently issued fresh-cut guidance that was
12 mentioned several times this morning. She is going to
13 briefly summarize for us issues and questions posed in
14 the notice of hearing. That will set the stage for the
15 public comment this afternoon.

16 MS. GREEN: Welcome to the second part of our
17 program. As Mike said, I'm going to talk to you about
18 issues and questions in the Federal Register notice. I
19 just want to -- after that, we'll have a comment from
20 the public commenters. If you remember, this second
21 half of the purpose of this meeting was to solicit
22 comments from the public. So let me start with -- I'm

1 going to start with the issues.

2 There are five issues in the Federal Register
3 notice. The first issue has a lot to do with risk
4 factors. There are four questions, so that one has more
5 questions than any of the other issues. The second
6 issue has to do with FDA measures -- the measures that
7 FDA has already taken and the measures that they may
8 take in the future. The third has to do with traceback
9 and the challenges to tracking a product through the
10 supply chain. The fourth issue has to do with records,
11 not the traceback records but the written food-safety
12 program SSOPs, monitoring records -- those types of
13 records. Then the last issue has to do with
14 verification. And it's verification that the good
15 agricultural practices have actually been following.

16 Issue 1 deals with risk factors throughout the
17 entire supply chain for each industry sector. So this
18 is quite a mouthful.

19 Here's a very simple supply chain. So the
20 risk factors we're talking about would be those that are
21 involved in production; and there are many steps through
22 production that you have to look at: Harvesting; post-

1 harvest processes like cooling and packing; then
2 processing, if it's a fresh-cut product; and all of the
3 steps in processing from receipt to distribution. Then,
4 also, it includes the consumer -- going to the consumer
5 and what kind of practices should the consumer use to
6 prevent contamination from occurring.

7 There are some risk factors that apply to
8 multiple stages in the supply chain; and I've just
9 picked three that we think are extremely important.
10 You've heard a lot about water today -- agricultural
11 water in production; processing water, processing fresh-
12 cut produce; or cooling water and cooling the produce in
13 a post-harvest practice.

14 The second risk factor is worker health and
15 hygiene; and I just want to add to that it's not just
16 worker health and hygiene; actually, it's food handler
17 health and hygiene and also food-safety practices that a
18 particular food handler uses. That, you can see, would
19 apply to almost every step in the supply chain.

20 And then the last risk factor that I have up
21 here is the environmental sources of contamination,
22 which you know often are thought to be in the production

1 environment, but it can also mean the processing
2 environment, the adequacy of sanitation programs to
3 clean the facility.

4 This is the first question in the four. First
5 issue: What are the practices that contribute to risk?
6 What are the risky practices at each stage of the
7 produce supply chain? So this question is basically
8 identifying what the risk factors are throughout the
9 entire supply chain.

10 And the second question is, How can we change
11 those practices to reduce risk? What can we do?

12 And the third question: What current
13 practices reduce risk? And is there data to support
14 that, like data saying that GAPs guidance is being
15 followed?

16 Question 4 is -- and I think we heard Hank
17 talk about this a lot today -- is fresh produce or input
18 such as agricultural water sampled and tested for
19 pathogens or indicator organisms at any stage of the
20 supply chain? If yes, then please describe the sampling
21 and testing done. And we heard a lot about sampling and
22 testing that's being done with -- I guess -- in regards

1 to best practices that at least Western Growers are
2 promoting.

3 So sampling can be done at any point in the
4 supply chain. It can be done with -- actually, we just
5 finished an environmental study on the Eastern Shore in
6 pond water -- pond water that was used for irrigation.
7 It can be done in the processing facility, on food
8 contact surfaces, water.

9 The second issue has to do with the FDA
10 measures. And FDA has implemented a lot of different
11 measures and we heard about them from Michelle this
12 morning. Some of the measures -- I'll just repeat what
13 some of the measures are: The 1998 Good Agricultural
14 Practices Guide, the fresh-cut produce guide. We've
15 issued quite a bit of guidance. We've issued letters to
16 industry. We also call that guidance to both the tomato
17 and lettuce industries and we developed the 2004
18 produce-safety action plan. Last year we started the
19 lettuce and leafy-green initiative. And, actually, the
20 public hearings were also some measures that were taken
21 to ensure the safety of fresh produce.

22 So what should we do next? What new federal

1 actions are needed to enhance the safety of fresh
2 produce? Are there federal actions that are needed and
3 where should they focus in the supply chain?

4 There's wide variation in the industry. How
5 flexible should we be? These are the types of
6 variations. I think we've heard about these too. The
7 size and type of establishments is really highly
8 variable. The nature of the commodities: Is it grown
9 on the ground? Is it grown on a bush? The practices
10 used in production change from commodity to commodity
11 and, as we heard today, from region to region. And the
12 vulnerability of a particular commodity to
13 contamination.

14 One challenge faced by public health officials
15 during an outbreak is to quickly identify through
16 tracebacks the source of contamination. When an
17 unpackaged or raw agricultural commodity is involved in
18 an outbreak, there may be several packing and repacking
19 establishments and multiple opportunities for mingling.
20 So traceback with produce is very difficult. Produce is
21 perishable. Some produce is not packaged or labeled.
22 Even with packaged and labeled produce, traceback can be

1 difficult because there may be insufficient records to
2 identify the farm or field; and there may be
3 discrepancies between the records of incoming and
4 outgoing product.

5 Question 7: What types of records and other
6 information from what types of facilities would be most
7 useful in facilitating traceback efforts? These are
8 traceback records.

9 Issue 4: It's about records other than
10 traceback records, such as written food-safety plans,
11 SSOPs, monitoring records, training records, records
12 than can be used as tools for both industry and
13 regulators -- for industry, to conduct operations that
14 will enhance the safety of fresh produce and for
15 regulators to verify that certain practices are being
16 followed.

17 For growers, an assessment of field
18 environment and agricultural inputs is also important
19 because it could contribute to the development of
20 records, written food-safety plans, and SSOPs that it's
21 sort of like a hazard analysis in a hazard plan where
22 the grower will look at the process -- at the production

1 process -- and actually identify areas where controls
2 are needed. It could also help to determine what
3 factors should be monitored and the frequency of
4 monitoring.

5 Question 8: Are written food-safety plans,
6 written SSOPs, periodic assessments, training and/or the
7 establishment and maintenance of records useful for risk
8 identification and risk mitigation or management
9 purposes? And to what extent are these practices in
10 place? And in what sectors of the industry?

11 The fifth issue and the last issue has to do
12 with verification; and it's verification -- we have
13 heard today, too, that some buyers are now requiring
14 that producers and other suppliers provide self and/or
15 third-party audit verification that showed that they're
16 following the GAPs guide. But we don't know how the
17 extent to which these verifications actually reflect
18 adherence to the guidance.

19 Question 9: How should adherence to the GAPs
20 guide or new produce safety guidance be measured and
21 verified by the grower or operator, government
22 regulators, or third-party auditors in the event of any

1 new recommended federal action or in the event you are
2 not recommending any new federal action?

3 And the last question is, if you're
4 recommending any new measures, describe how they may
5 affect small businesses such as roadside stands, farm-
6 gate operations, farmers markets, or other small
7 businesses involved in direct sales.

8 So that is all of the questions and issues.
9 I'll just talk a little bit about the public comments.

10 Speakers will be limited to approximately five
11 minutes. We have a little bit more time, but we are
12 going to try to keep you within five to ten minutes.

13 Speakers will be heard in the order in which they
14 registered, so as the speaker before you is ending his
15 or her comments then start making your way to the front
16 of the auditorium so you just speed up the process.

17 Now, these are oral presentations at a public
18 meeting, but we also are interested in getting whatever
19 data and information or comments that you have; and you
20 can submit electronic comments until June 13th to this
21 Web address. This address is in the Federal Register
22 notice. You can submit written opponents to this

1 address. This is also in the Federal Register notice. I
2 think everybody should have one if they have a packet.
3 Make sure you include the agency name and docket number
4 -- the docket number, again, is 2007N-0051 -- on your
5 comment submission.

6 MR. LANDA: Thank you.

7 First speaker this afternoon is Senator
8 Florez, California State Senate.

9 SENATOR FLOREZ: Thank you very much. I do
10 appreciate the opportunity to say a few words to our
11 FDA. And I want to thank you for holding this public
12 hearing and creating a forum where all those that are
13 interested can come to speak on this very important
14 topic.

15 First and foremost, I should say that,
16 obviously, in California this is of great interest,
17 given the amount of spinach that we grow for the nation.
18 I should tell you that a very quick review of the
19 current history of this epidemic of E. coli shows that
20 government action, and government action alone, has been
21 the sole impetus for change in this industry.

22 And I'd like to tell you why. I think it's a

1 question of what type of government action. Obviously,
2 we are in favor of the government action that is more on
3 the demanding side rather than, if you will, on the
4 asking side. So let me go through and tell you why I
5 believe that should be the case as we move forward.

6 First and foremost, I want to say that the FDA
7 issued voluntary good agricultural and manufacturing
8 practices as far back as 1998. In fact, in 2004 the FDA
9 issued a product safety action plan, yet nothing
10 changed. The FDA even sent two open letters to
11 California, one in February of 2004 and one in November
12 of 2005, raising concerns about continuing outbreaks,
13 yet nothing happened. It wasn't until the FDA finally
14 put its foot down and issued a nationwide advisory
15 against eating bagged spinach did we see any significant
16 action by the industry. And, in fact, in this case it
17 wasn't the marketplace that grabbed the industry's
18 attention. Obviously, it was government action taking,
19 if you will, action on behalf of the health and safety
20 of consumers throughout the nation that made this
21 happen.

22 The only question I believe that should be

1 before you today is how long we have to wait until
2 government steps up to the plate and takes serious
3 action on this issue. For consumers, this translates
4 into the question of how many more people have to get
5 sick; how many people will die; and, ultimately, what we
6 need to do in government to best to protect them.

7 I can tell you that the industry, which you
8 probably heard today, has repeatedly made the argument
9 that market forces are sufficient to cause change in the
10 industry and that we should rely somehow wholeheartedly
11 on the industry, in essence, to fix this epidemic
12 themselves.

13 I can tell you that the most obvious rebuttal
14 to this argument is the fact that we have had twenty-two
15 outbreaks of E. coli in leafy greens since 1995. We
16 have had three outbreaks in the last six months alone.
17 And if market forces are going to work, they should have
18 worked by now; and they would have worked, but that has
19 not happened.

20 Maybe, hopefully, the industry will argue that
21 they have finally lost enough money to do something
22 about this this time. But the question for many of us,

1 particularly in government, is how many more consumer
2 deaths are acceptable? Consumers, our citizens, deserve
3 the best food safety system, not food safety determined
4 by whether they are inside or outside of the acceptable-
5 loss category. Food safety by collateral damage, in our
6 view, is not what people elected their government
7 officials to protect them and provide for.

8 However, the real fallacy of the industry's
9 argument, in my view, is revealed when you look behind
10 the market forces that are actually behind the leafy-
11 green industry. There are many market factors that
12 people don't talk about. However, I think the most
13 important are actions such as was taken just today in
14 Los Angeles, where one large shipper said they would not
15 take product anymore, if you will, if it was grown with
16 recycled water or compost of a nature that would not
17 necessarily lend itself to health standards. That is a
18 marketing force in itself. They should change because
19 of that. And, yet, when not everyone signs up for that
20 program, it leaves the window open for those to say that
21 this doesn't in any way a level playing field on which
22 to have, if you will, a standard that makes people feel

1 better about what is in their spinach.

2 I can tell you that in our thought process, we
3 are very culpable in government in terms of this
4 particular issue. I think the FDA needs to step to the
5 plate. I believe it's not enough to issue good
6 agricultural and manufacturing processes to growers and
7 processors, yet fail to mandate these practices and
8 demand that they be implemented. It's very good and
9 fine that after seven years of issuing good agricultural
10 practices yet again. But I think here is at this point
11 in time from our vantage point we have to say that we
12 have to make these mandatory. And letters urging
13 California to do anything at this point, at least in
14 terms compliance, from my point of view in terms of this
15 are simply insufficient.

16 I can also tell you that California's
17 government is equally to blame. The California
18 Department of Health Services and the Department of Food
19 & Ag repeatedly received warning letters from you folks,
20 the FDA, yet failed to take any necessary steps to
21 mandate compliance. I learned in testimony before a
22 select committee on foodborne illness that the

1 Department of Health Services didn't even know whether
2 it had followed up on investigations had been conducted
3 on farms implicated in past E. coli outbreaks. And, in
4 fact in their testimony, they didn't know whether they
5 had followed up; and after question after question, it
6 started to concern us that when they issued reports on
7 E. coli, when there are specific recommendations, and
8 our own department of health services hasn't followed up
9 to see if those changes have taken place that we have a
10 problem in the State House as well. I can tell you that
11 what is even more concerting (sic) when corrective
12 actions were talked about at this hearing. In fact, the
13 Department of Health Services detailed in their own
14 investigative reports that had been implemented in the
15 fields that these actions had not yet taken place and,
16 in fact, we believe that issuing broad recommendations
17 have no weight and, in fact, no enforcement value when
18 it come to our own investigations in the state.

19 As you probably know, we are waiting for the
20 latest report. Apparently, there is a joint effort by
21 the FDA and the State of California. We are still
22 waiting for those edits. We are still awaiting the

1 report. We are very anxious at the state level to have
2 a hearing on that report, so I would urge you as quickly
3 as possible to release that report so we can get on our
4 business at the state to take this issue apart and put
5 it back together and find out ultimately what is the
6 best way to mandate, if you will, these practices that
7 will give consumers the best possible produce.

8 Let me also say that despite all of these
9 outbreaks and these hearings, the California Department
10 of Health Services, the California Department of Food &
11 Ag, along with the Governor, continue to support
12 industry self-regulation in some sort of marketing
13 agreement.

14 Over the past few months I have heard a lot of
15 support for self-regulation based upon the speed of that
16 implementation; self-regulation is somehow the fastest
17 way to change the market. And I can tell you at least
18 from my vantage point fast does not mean safe. I think
19 at the end of the day, we are very interested in
20 anything that has a higher benchmark than speed. And so
21 we should instead be asking ourselves, quite frankly,
22 what is the best plan? What is the safest plan? What

1 is the long-term plan in terms of making leafy greens a
2 much better product in terms of California produce?

3 I can't tell you that the current marketing
4 agreement is good. It covers about ninety percent at
5 best. And because it only covers ninety percent of the
6 produce that comes out of California, I believe it gives
7 us a ninety-percent plan. And I believe that a ninety-
8 percent plan is unacceptable. I think what consumers
9 absolutely want is a plan that covers industry one
10 hundred percent of the time. That means, if you will,
11 that best plans guarantee that every farm every day have
12 these practices being implemented on a consistent basis.

13 I'm not sure we can say that under the current self-
14 regulatory marketing agreement -- the marketing-order
15 approach.

16 I believe that the only way to guarantee this
17 is thorough a government-mandated approach, obviously,
18 to make sure the State of California takes action. And
19 in that regard we've introduced three bills. I'm sure
20 you're all aware of them. The bills, in essence, deal
21 with pre-outbreak authority to inspect growers; to test
22 water and soil and produce; as well as the power to

1 quarantine, destroy, and recall produce determined to be
2 infected. These are all powers the agency -- the
3 Department of Health Services -- currently doesn't have.
4 Our state veterinarian has those powers, but somehow our
5 State Department of Health Services, when it comes to
6 leafy greens and other types of produce, doesn't have
7 that power. We'd very much like them to have that
8 power.

9 I believe that just as milk is a product that
10 everyone counts on, no less so for produce, particularly
11 spinach. We should have the same types of authorities
12 when it comes to produce in California.

13 Let me also say that the bills authorize, if
14 you will, and push forward good agricultural practices
15 in the form of regulation. We want to make sure that
16 any good agricultural practices is put in statute, that
17 flexible regulations are put forth from that statute;
18 and those regulations allows, if you will, the science
19 to prevail on an ongoing basis. So things are very
20 flexible but at the end of the day we need something to,
21 in essence, enforce. And the only way to do that is to
22 make sure that there is something in law to enforce. So

1 this bill would, in essence, allow those opportunities.

2 I should also say that, obviously, good
3 agricultural practices are very important to the state
4 of California, to the industry, and to everyone in the
5 State House. However, they need to be in statute and
6 they need to be put forth in terms of regulation and
7 need to be enforced by health officials.

8 The last bill of ours is something that I
9 mentioned earlier and it has to deal with traceback. And
10 there's no doubt that as we wait for the upcoming report
11 on FDA/California, we need a better traceback system
12 that will allow us to, in essence, get to the processor,
13 the grower, the distributor, the retailer quickly; that
14 won't push us -- or you -- to actions that somehow
15 blanket the entire industry. As has been mentioned, we
16 lost about a hundred million dollars in economic value
17 due to spinach earlier this year. We think a traceback
18 system that is much more specific and modeled maybe
19 after the strawberry commission's traceback system would
20 work very well with leafy greens.

21 I've said enough, but let me simply say, if I
22 could, as I stated that the highest public official in

1 the State of California -- and that would be the
2 governor -- and many of our federal representatives that
3 the message on the wall is very clear. We do not
4 believe time is a luxury; and we do not believe that we
5 can afford, if you will, a voluntary action that, if you
6 will, a regulatory action is absolutely required in this
7 case. The next outbreaks really should not be on all of
8 us who are, in essence, pushing a voluntary approach. I
9 think that the next outbreak will be on those who don't
10 mandate a better approach. And I think that's all of us
11 here sitting here in government, particularly those who
12 are elected to protect the health and welfare of their
13 citizens.

14 Lastly, let me say that when we think about
15 those losses, we always turn back on our committee to
16 those who lose real children, real grandmothers, real
17 aunts and uncles and parents -- those who, in essence,
18 will look us in the eye and ask the question, Did you do
19 everything you could? Have you done everything you
20 could have to make this product safe?

21 I think at this point in time, I don't believe
22 consumers have confidence because they're skeptical. And

1 they should be skeptical, because any plan that's less
2 than a hundred percent is not going to bring back
3 consumer confidence. And I think at the end of the day,
4 really beyond making a safe product that's what's going
5 to make all of this process work much better.

6 I can tell you that at least we're moving our
7 bills through, that we're going to try our best. We're
8 going to push as hard as we can on the edges to have the
9 highest standards. We do appreciate all of the
10 statements by the FDA today that we'd better take this
11 seriously, we'd better have high standards, and we'd
12 better make sure that we enforce those. And I can tell
13 you our bills attempt to do that. Hopefully, we've
14 offered our best in that regard.

15 And I do want to thank you for having us; and
16 I appreciate the opportunity today. Thank you.

17 MR. LANDA: Thank you.

18 Is Mark McAfee here?

19 Edward Beckman from California Fresh Tomato
20 Growers.

21 MR. BECKMAN: Thank you for this opportunity
22 to address the FDA as well as those who are in the

1 audience today.

2 My name is Ed Beckman. In my current
3 position, I serve as President of California Tomato
4 Farmers. We are a cooperative that represents really
5 about nine out of ten fresh tomatoes that are produced
6 in California. Previously I served as CEO of the
7 California Tomato Commission, a mandated state program
8 that developed the first commodity-specific GAP document
9 back in 1999. And in 2006 we were able to amend
10 California's agricultural code to strengthen the
11 traceback provisions as they applied to fresh tomatoes.
12 I am also cofounder of the North American Tomato Trade
13 Work Group, which goes by the acronym NATTWG. It is an
14 association of producers from throughout North America
15 in response to the 2004 directive of the FDA to the
16 lettuce and tomato industries to develop commodity-
17 specific guidance documents. We took charge of that
18 task, and I was the project leader.

19 I thought it would be appropriate to share
20 with you some of the lessons that we learned from the
21 development of this GAP document.

22 First off, we found out that adherence to GAP

1 is at the highest in California and also in Florida, the
2 largest producer for fresh tomatoes. The vast majority
3 of producers at the time that we began the development
4 of this document were already employing third-party
5 verification of their GAP practices. However, we found
6 significant evidence to conclude that those who were
7 smaller and more seasonal producers were not following
8 GAP protocol in their production. This, in part, was
9 due to the fact that (a) the economy of scale of farming
10 were prohibiting that, at least in the growers' mind;
11 and, number two, that the sales to other than major
12 food-service and supermarkets did not require third-
13 party verification of their agricultural practices.

14 Another key issue that we learned in the
15 development of this GAP document was the fact that the
16 standards employed by the grower were not always
17 maintained in the distribution channel, meaning that
18 those actually who purchased and then resold the product
19 were often ultimately responsibility for quality. We
20 found that traceback, or the lack thereof, was a concern
21 as well as certain practices related to fresh-cut
22 tomatoes, where ice baths were used to firm tomatoes for

1 slicing, which may increase risks. Again, we found that
2 standards employed by the grower were not always
3 continued all the way through the distribution chain.

4 I would say, since we began the development of
5 that document back in 2004, there has been a significant
6 advancement by the practices of industry. We've also
7 paid very close attention to what science exists; and
8 now today we recognize the first GAP document that was
9 produced just last year is now outdated. And,
10 therefore, our members are now working with FDA and the
11 California Department of Health Services and our
12 counterparts in Florida as well as those from Mexico and
13 Canada as we form a team that will begin the development
14 of new guidance in a very transparent environment.

15 That said, there are farmers who want more --
16 farmers who want a national standard. And because of
17 that fact the members of California Tomato Farmers this
18 year are moving to mandatory GAP, starting in June. We
19 are doing so because there is no mandatory GAP standard
20 and it is unlikely that we will see a standard in the
21 near term. Our members believe that it is time to
22 become more proactive on the establishing and

1 endorsement of such standards. And this is a supply
2 effort that is taking place today on the other side of
3 the country in Florida, where there is now pending
4 legislation that will require production under verified
5 good agricultural practices that would become effective
6 this fall.

7 So, again, the California Tomato Farmers begin
8 this summer employer mandatory GAP in the production of
9 our tomatoes. To ensure compliance, we'll include
10 verification by government authorities. And the metrics
11 we will be using will be based very much upon a national
12 standard that is under consideration by both California
13 and Florida, with the understanding there must be
14 consideration given to the production practices in each
15 state. However, the problem we have now is with
16 California and, also, with Florida moving to mandatory
17 GAP, we have roughly seventy percent of the tomatoes in
18 the United States produced under mandatory GAP
19 standards. It does represent an impressive start.
20 However, we were very much in agreement that when we
21 decided to go down the path towards mandatory GAP, there
22 was much more to be done; and, therefore, we do

1 represent, again, nine out of ten tomato growers in the
2 state saying that we believe there needs to be a move to
3 a mandatory standard that is based upon sound science,
4 one would that require production under GAP by all
5 tomato producers in all states, and, further, that
6 imports that supply upwards of thirty percent of the
7 nation's supply of fresh tomatoes be subject to the same
8 standards.

9 We're committed to finding a short- and a
10 long-term solution to the problem. We recognize that
11 there are environmental factors in the East, which you
12 heard about this morning, where most of the outbreaks
13 involving fresh tomatoes have originated, are the
14 primary cause of Salmonella. However, we also believe
15 that all growers, no matter where you produce, must
16 learn from these unfortunate events and understand the
17 risks that can exist in production.

18 As you also heard this morning, in response to
19 the concerns of the tomato industry, in the last month,
20 the Maryland Joint Institute for Food Safety and
21 Nutrition, the University of Florida, and FDA held a
22 workshop to prioritize the research needs of the

1 industry related to reducing if not eliminating the
2 food-safety contamination at any point in the production
3 and distribution chain of fresh tomatoes. There are a
4 number of questions today that we don't have answers
5 for. And that, we believe, should be just as much of a
6 priority as seeking regulation of tomato production
7 based upon a mandated GAP program.

8 Briefly, several issues that I think warrant
9 further investigation:

10 Are there specific seasons, microclimates, or
11 weather events associated with the contamination of
12 tomatoes? Previously, the identification of such risk
13 factors could lead to practical guidance. Such guidance
14 would be an important determination in the development
15 of different implementation and intervention strategies
16 for the various production regions.

17 Number two, what vectors and vehicles are
18 important in transmitting pathogens to tomato plants and
19 fruits? A number of scenarios have been presented;
20 however, we don't fully understand the importance of
21 those vectors and vehicles; and without such knowledge
22 the science-based selection of risk-mitigation

1 strategies is not possible and we're using a much less
2 focused approach than we would like.

3 And, number three, what are the cooling and
4 cold-chain requirements that are needed to prevent
5 growth of pathogens on tomatoes? As I've indicated,
6 what we learned from the development of the first GAP
7 document is that there were not consistent practices all
8 the way through from farm to fork. And that is a
9 concern. There's very little information available to
10 assess what portion of the microbiological food-safety
11 risks associated with tomatoes are due to inappropriate
12 temperature being both too warm or too cold. And that
13 is a question that needs to be answered.

14 I will also say that these three issues only
15 represent the beginnings of the research. The question
16 is, of course, where are all the funds going to come
17 from to be able to go out and find the research as well
18 as the researchers and the funding mechanism to complete
19 this task.

20 So, in summary, while the fresh tomato
21 industry, I believe, has responded to the conditions
22 that FDA represented in their 2004 letter to the

1 industry that we develop commodity-specific guidance
2 guidelines, I believe that we are going past that. We
3 are joining with our counterparts in Florida to enact
4 mandated GAP. We recognize still only that's only one
5 step toward finding a final solution. That final
6 solution, we believe, requires a national action plan.

7 A second guidance document is under
8 development. We hope to have that published by the end
9 of this year.

10 And then, again, one major task that I would
11 ask you to take into consideration -- and that is the
12 need to better understand the problem at hand and how we
13 can craft a long-term solution. We believe that
14 research represents a major task that will provide a
15 true long-term solution to the issue of food safety in
16 the United States.

17 Thank you.

18 MR. LANDA: Thank you. Can you stay for some
19 questions?

20 MR. BECKMAN: Yes, I can.

21 MR. LANDA: Any questions?

22 Ms. McGarry?

1 MS. MCGARRY: Traceback of tomatoes and other
2 produce classes as well has been challenging. What are
3 some of the efforts being put forth in your industry to
4 improve the traceability of tomatoes?

5 MR. BECKMAN: Well, there are several issues.
6 One in California we went to actually -- carton labeling
7 provides grower and lot identification. The biggest
8 challenge that we have has been in the commingling of
9 product at the repack level; and that remains a concern.

10 The basis for our discussions has been with
11 the trade -- those who are involved in handling our
12 product -- to understand that any commingling of product
13 -- for example, the commingling of product that was
14 washed versus unwashed -- poses an unreasonable risk.
15 We also addressed with USDA as well as PACA the whole
16 issue of the problem of product commingling. Again, I
17 don't think there's a final solution yet on that issue.

18 MR. LANDA: Mark Roh.

19 MR. ROH: Thank you. You mentioned that with
20 your partners in Florida you were developing mandatory
21 GAPs. Is that through some sort of state legislation or
22 some other mechanism?

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Page 181

1 MR. BECKMAN: Mandatory GAP in Florida is
2 being developed through state legislation. In
3 California, we have formed an agricultural cooperative
4 that makes GAP, as well as verification by USDA in
5 addition to other third-party auditors, a requirement
6 for membership in the cooperative.

7 MR. LANDA: Dr. Buchanan.

8 DR. BUCHANAN: Earlier in your comments you
9 indicated that you had done some work examining what
10 percentage of people in the tomato industry were
11 following GAPs in California. Do you have any -- is any
12 of that data available? And can you share that with us?

13 MR. BECKMAN: There was research that was done
14 two years ago at the time the letter came out from FDA
15 in 2004 to determine what the compliance rate was. At
16 that time the compliance rate was estimated at eighty
17 percent. We estimate that has now increased.

18 MR. LANDA: I think you mentioned in Florida
19 as well in terms of evaluating adherence. Was that also
20 eighty percent?

21 MR. BECKMAN: I can't speak to what the level
22 of GAP implementation adoption was in Florida at the

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1 time of the survey.

2 MR. LANDA: Ms. Bohm.

3 MS. BOHM: You mentioned that tracebacks, or
4 the lack of tracebacks, was a concern. Would you be
5 able to specifically comment on what could improve that
6 situation in fairly specific terms?

7 MR. BECKMAN: Well, I think the specific issue
8 we must look at is what is done at the repack levels to
9 provide positive lot identification and simply to
10 prohibit the commingling of product. That is a common
11 trade practice that needs to be concluded.

12 MR. LANDA: Any other questions?

13 Thank you, Mr. Beckman.

14 The next speaker is James Gorny, with the
15 United Fresh Produce Association.

16 DR. GORNY: Good afternoon. My name is Dr.
17 Jim Gorny. I am the senior vice-president of good safety
18 and technology for United Fresh Produce Association.

19 Our trade organization represents more than
20 twelve hundred growers, packers, and shippers of fresh-
21 cut fruits and vegetables as well as raw agricultural
22 commodities. This accounts for the vast majority of

1 produce grown and shipped in the United States. We
2 bring together companies across the produce supply chain
3 from farm to retail including all produce commodities,
4 both raw agricultural products and fresh-cut ready-to-
5 eat fruits and vegetables from all regions of
6 production.

7 I mention these characteristics today because
8 our organization's views on food safety are shaped by
9 this broad, diverse membership across the entire produce
10 industry, not by one sector or one region of the
11 industry. Within our industry there is always diverse,
12 robust, and strongly held views on every issue,
13 including food safety. Our association attempts to
14 develop the best overall industry policies and
15 practices to best serve the American consumer.

16 Let me begin by repeating something that's
17 been said many times and will be said many times again
18 and again. Food safety is our industry's top priority.
19 I personally know many of the men and women who grow,
20 pack, prepare, and ship product; and they are committed
21 to providing consumers with safe and wholesome products.

22 I would also like to say that the spinach

1 outbreak last fall was a tragic occurrence. And on
2 behalf of the entire industry, let me say that our
3 hearts go out to all those who became seriously ill or
4 died.

5 We can never forget the real human impact when
6 something goes wrong in our food system. That's what
7 drives food safety to be a process of continuous
8 improvement and not a static achievement. We are on a
9 continuum, constantly striving towards perfection; but
10 we heard earlier today that, scientifically, perfection
11 and zero risk is simply not possible. American
12 consumers safely consume over a billion servings of
13 fresh fruits and vegetables every day. But our industry
14 cannot rest when even a rare outbreak in the food-safety
15 system can cause such an impact on human health and
16 well-being, such as was felt last fall.

17 Let me allay any concerns that our industry
18 has just now begun to address the food-safety issue. Our
19 association first published food-safety guidelines for
20 the fresh-cut produce industry over fifteen years ago,
21 in 1992. We are now on our fourth edition. We also
22 work with Western Growers and others to provide good

1 agricultural practices in the mid '90s. And our mission
2 has been to serve the American public for many years.
3 When a tragedy such as the E. coli O157:H7 outbreak
4 occurs, we're committed; and that's why we're here
5 today, to learn all the lessons possible and incorporate
6 what knowledge we can learn into the continuing process
7 of improvement.

8 I want to address two main points today.
9 First, I want to talk specifically about what our
10 industry has done since the outbreak and what we are
11 doing to improve food safety.

12 And, second, I want to share what our
13 association's views are on the most appropriate produce-
14 safe regulatory framework to protect public health.
15 When the spinach outbreak occurred, our entire industry
16 immediately pulled all spinach from the shelves
17 nationwide and cooperated fully with FDA in tracking
18 this problem back to its source. That total industry-
19 wide shutdown was, quite frankly, unprecedented in
20 response. But FDA felt it was necessary until they were
21 certain that any and all contaminated product was
22 removed from the marketplace.

1 In fact, we now know that the only
2 contaminated product came from one fifty-acre farm,
3 packaged in one processing plant, and only on one
4 production shift. That's out of more than 300,000 acres
5 of lettuce, spinach, and leafy greens grown in the
6 region, where this product was grown in dozens of
7 processing plants around the country. But when faced
8 with an immediate public health question, we agreed with
9 the FDA to err on the side of caution.

10 Once we averted the outbreak, our industry
11 also immediately began a comprehensive reevaluation of
12 spinach production, handling, and processing to make
13 sure that we are taking all the appropriate steps to
14 assure the safety of these products. This included not
15 only the company directly involved in the outbreak but
16 companies throughout the spinach supply chain that were
17 growing and processing in this sector. While the source
18 of the outbreak itself proved to be narrow, the entire
19 industry joined together to make sure we collectively
20 addressed all the common risk factors that can be
21 associated with fresh leafy greens which are grown
22 outside in nature and consumed without cooking.

1 This effort has led to important initiatives
2 spearheaded by the lettuce and leafy-greens industry to
3 adopt stringent food-safety measurement criteria which
4 can be implemented and verified across this sector of
5 the industry. The California Department of Food and
6 Agriculture has recently adopted a lettuce and leafy-
7 greens marketing agreement which will serve as a means
8 of verifying rigorous compliance of safety for lettuce
9 and leafy greens from this major production region.

10 We also believe similar standards must apply
11 nationally and internationally; and I'll address those
12 issues specifically in a moment. What we have developed
13 are science-based standards, including careful
14 attention to site selection for growing fields based on
15 farm history, proximity to animal operations,
16 appropriate standards for irrigation water and other
17 water that can come in contact with crops; prohibition
18 of raw manure with use of only certified safe
19 fertilizers; good employee hygiene in the field
20 handling; and, of course, strong food-safety controls in
21 all food-processing plants.

22 Under the leafy-greens agreement, handlers

1 will be audited by the CDFA to ensure that they are
2 complying with these standards; and they will face
3 penalties if they are found not to be in compliance --
4 and the ultimate consequence of not being allowed to
5 sell their product if they don't comply. Taking this
6 step toward self-regulation for the private industry
7 sector has been not been an easy task. But we believe
8 this is a critical step in continuing to assure the
9 public that our industry is doing everything possible to
10 make our product safe.

11 I want to publicly recognize those brother
12 shippers and processors of leafy greens who have made
13 this commitment.

14 Stepping out now to a national and multi-
15 commodity perspective, I can tell you that many other
16 sectors of our industry are pursuing similar efforts to
17 define and implement and verifying best practices from
18 field to table. We've heard about a number of those
19 today from the tomato industry, both in Florida and here
20 in California.

21 Also, I had the opportunity to meet with
22 growers in New Jersey a few weeks ago, where a new food-

1 safety task force has been put together by their
2 department of agriculture and is looking at specific
3 GAPs and training programs for growers. Another good
4 example is the Georgia Fruit and Vegetable Growers
5 Association, which has its own GAPs training program to
6 help small growers in the state to better understand and
7 apply best practices. All these efforts represent
8 industry-led initiatives to further reduce risk and
9 ensure the safest possible produce for the public.

10 It's within this context of all these
11 industry-driven numbers that I turn now to discuss what
12 we believe to be the most appropriate regulatory
13 framework for fresh-produce safety. While there's much
14 our industry can and must do, we also have to recognize
15 the important role of the federal government. Today our
16 country faces a critical public health challenge to
17 increase our consumption of fresh produce. The 2005
18 U.S. dietary guidelines calls on all Americans to
19 literally double their consumption of fresh fruits and
20 vegetables. And now our nation is faced with an obesity
21 crisis that threatens the long-term health of our
22 children unless we radically change our eating habits

1 and help them make good lifetime choices.

2 I'm here today because I fear that if we not
3 ensure public confidence in the strong, credible, and
4 comprehensive food-safety regulatory framework, we are
5 putting that goal at risk. It is simply unacceptable
6 for Americans to fear consuming the very fruits and
7 vegetables that are essential to their good health. Our
8 industry can have but one goal in food safety; and it
9 starts with the consumer. We believe consumers must be
10 able to shop at any grocery store, order produce at any
11 restaurant with complete confidence in the produce
12 selection, that it is safe and wholesome for them to eat
13 and a healthy choice. Put simply, fear has no place in
14 the produce department. Whatever the risk that might be
15 present must be viewed as an acceptable risk, based on
16 strong government assurance that proper food-safety
17 systems are in place and that the benefits of
18 consumption far outweigh the low risk.

19 I'm personally confident about the choices
20 that I make today because I know many of the people who
21 grow, ship, and process produce items. I know a lot
22 about the industry. I know about the practices that

1 have been implemented, all the measures that they're
2 taking to assure produce and food safety. I also know
3 how our team at United Fresh is working to make sure
4 every corner in our industry is focused on food safety.
5 But no matter how hard our industry works, public
6 confidence ultimately depends on government as the final
7 health and regulatory authority. They must determine
8 that proper food-safety standards are in place and that
9 they ensure they are being met.

10 Let me review three key principals we believe
11 at United Fresh to be critical for our nation's food
12 supply regulatory framework.

13 Number one, we need consistent produce food-
14 safety standards. We believe produce food-safety
15 standards must be consistent for individual produce
16 commodities grown anywhere in the United States or
17 imported into this country. Consumers simply must have
18 confidence that the safety standards are met, no matter
19 where the commodity is grown or processed. Because of
20 the variation in our industry's growing and harvesting
21 practices in different climates and regions, flexibility
22 is very appropriate and necessary. For example, some

1 production areas use deep wells for irrigation while
2 others use river water supplied by dams. Some farmers
3 use overhead-sprinkler irrigation. Others use drip
4 systems laid on the ground. Other use furrow
5 irrigation. But the common factor must be that all uses
6 of water for irrigation must meet safety standards that
7 protect the product. That must be true whether the
8 product is grown in California, Florida, New York, or
9 Mexico. We strongly applaud the industry groups in
10 different states and regions that are working to enhance
11 local practices. Their work demonstrates the industry's
12 commitment to do all that we can to enhance safety in
13 growing and handling. But to build consumer trust,
14 strong scientific standards that were developed for one
15 region can only be successful if applied consistently
16 across the industry.

17 Our second major point: Federal oversight and
18 responsibility. We believe achieving consistent produce
19 safety standards across the industry requires federal
20 government oversight and responsibility in order to be
21 most credible to consumers and equitable to producers.
22 We believe that the USFDA, which is the public health

1 agency charged by law with ensuring the safety of the
2 nation's produce supply, must determine appropriate
3 nationwide safe standards in an open and transparent
4 process with full input from states, industry, academia,
5 consumers, and all affected stakeholders. We are strong
6 advocates for food-safety standards based on sound
7 science and clear consensus of expert stakeholders; but
8 in a situation where science tells us that there can be
9 no such thing as zero risk and there is no cooking step
10 for our products, the public must be able to trust an
11 independent, objective government body as ultimate
12 arbiter of what is safe enough. In the future we must
13 be able to stand side by side with government to
14 reassure the public that together we have done
15 everything necessary to implement and comply with strong
16 mandatory government standards that protect public
17 health.

18 Let me say here a word specifically about the
19 role of USDA in helping the industry enhance safety.
20 USDA is a strong ally and offers a number of means to
21 assist the produce industry in safely growing handling
22 and processing fresh produce. First, as a diverse

1 agricultural industry, marketing orders have been an
2 extremely useful means of setting quality standards,
3 conducting research, and promoting specific commodity
4 groups. These orders fall under the agricultural
5 marketing services of USDA and are increasingly being
6 looked at as a potential means to stimulate good food-
7 safety practices as well. Growers of the commodity can
8 come together and vote to require specific practices
9 that then become mandatory for all growers of that
10 commodity.

11 In addition, USDA through AMS offers auditing
12 programs that assist the industry in measuring GAPs,
13 good handling practices, and HACCP programs in
14 processing plants. These are good educational training
15 programs as well as a means to measure individual
16 operators' understanding of implementation of food-
17 safety practices. We believe these programs can be
18 helpful. They are an important element in enhancing
19 good food safety. Yet these programs are an important
20 means for specific sectors of the industry to enhance
21 performance; and long-term public trust requires that
22 FDA set the most appropriate regulatory safety

1 standards. That is simply a call the industry cannot
2 make alone. FDA must have the ultimate responsibility
3 to ensure that the industry is complying with these
4 standards. That does not mean that FDA has to hire five
5 thousand new inspectors to visit every farm in America
6 or travel around the world. But it does mean that FDA
7 must have relationships with other governments, the
8 USDA, state agriculture, and regulatory officials to
9 ensure that compliance is taking place.

10 Cooperative agreements that were discussed
11 earlier today between FDA and the states have been in
12 the past extremely effective in providing oversight of
13 food-safety standards. Our analysis -- our legal
14 analysis -- is that FDA does have the regulatory
15 authority today to promulgate any needed rules and
16 regulations; issue guidance that compels industry to
17 action; enter into agreements with states to provide
18 field investigations; and generally set all necessary
19 standards to protect public health.

20 Thirdly, the third important aspect of our
21 vision is commodity-specific scientific approach. We
22 believe food-safety standards must allow for commodity-

1 specific food-safety practices based on the best
2 available science in a highly diverse industry that's
3 more aptly two or three hundred industries, not just
4 one. For example, food-safety requirements for products
5 grown close to the ground versus tree crops need to be
6 significantly different because the risk factors are
7 different. This will be an extremely important point in
8 looking at the produce and looking at produce food
9 safety in the future. Government and industry alike
10 must be careful that broad strokes do not result in
11 requirements that should not apply to specific
12 commodities and do nothing to enhance food safety.

13 We support the FDA's scientific approach --
14 and, finally, a few short words about the fresh-cut
15 guidance document. We support FDA's approach to address
16 specific standards for fresh-cut processing as contained
17 in the agency's fresh-cut guidance document. We
18 strongly support HACCP and processing plants. Though
19 there's been criticism of this document, that it is not
20 mandatory, we believe that it essentially provides an
21 interpretation as to what processors must do to comply
22 with 110 CFR -- or 21 CFR 110.

1 In conclusion, let me return to the important
2 role of fresh fruits and vegetables in public health --
3 and we've got to assure public health. Of course any
4 reasonable person in the food industry would want
5 produce not only -- would want to produce only the
6 safest possible product. But for us somehow it seems
7 even more important because of the healthfulness of the
8 products we introduce. With that public health
9 imperative, we simply cannot allow fears of food safety
10 to keep people away from fresh produce. We as an
11 industry must do all we can to prevent these illnesses
12 and working hand in hand with government. We pledge to
13 support government efforts to provide a long-term
14 regulatory framework that assures the public that
15 appropriate safety standards are in place and are being
16 met by the industry. But together we can help consumers
17 enjoy an ever increasing array of safe, healthy, and
18 nutritious fruits and vegetables.

19 And I thank you for your time.

20 MR. LANDA: Thank you.

21 Any questions? Dr. Acheson.

22 DR. ACHESON: Dr. Gorny, thank you for that.

1 What's your opinion of a mandatory HACCP or
2 HACCP-like program on the farm?

3 DR. GORNY: It's a very good question.

4 I think we need potentially -- we need to not
5 confuse the difference between a HACCP-based approach
6 and a true HACCP program. I find it very difficult to
7 understand how we could have a HACCP program on the farm
8 based on the seven items outlined by NACNIF. I think we
9 can have a HACCP risk-based approach but I truly doubt
10 we can ever have HACCP on the farm. It's certainly
11 applicable to food-processing plants.

12 DR. ACHESON: As a follow-up to that, then
13 would you advocate that? A mandatory HACCP-like
14 approach? I think that's what you just said -- on the
15 farm?

16 DR. GORNY: A HACCP-based approach definitely.
17 I don't know another way to approach it.

18 MR. LANDA: Mandatory?

19 DR. GORNY: Mandatory HACCP-based approach? I
20 think it's the only way to do it. You've got to look at
21 all the risk factors.

22 MR. LANDA: Thank you.

1 Dr. Buchanan.

2 DR. BUCHANAN: Doctor, I'm a little puzzled by
3 one of your comments, where you desire to have an
4 oversight involvement by FDA in ensuring the safety of
5 products. A lot of this will be at some point feet on
6 the ground. That in no way indicated that we ought to
7 have more inspectors. You sort of implied that that was
8 not a necessary component. And I'm just trying to figure
9 out how the numbers add up. We --

10 DR. GORNY: Understood. I had to skip through
11 that part.

12 Certainly I believe that FDA needs more
13 resources. We need commitment from the Congress to
14 provide more resources to FDA. The President needs to
15 make that commitment. But we don't understand how it
16 would be possible to have FDA solely involved in produce
17 food safety. We believe that state cooperative approach
18 is probably the most appropriate, involving state
19 government, involving local government, because it is --
20 agriculture is just so diverse. So if you'd like to
21 have five thousand inspectors, I guess that's a
22 possibility, but I don't understand how that would work

1 potentially.

2 DR. BUCHANAN: I think the concern is we don't
3 need another unfunded mandate.

4 DR. GORNY: You have every right not to want
5 an unfunded mandate and I absolutely believe that more
6 appropriations are needed by FDA for research and/or
7 compliance.

8 MR. LANDA: In your model, then, would FDA
9 perhaps serve an auditing function for whoever did the
10 inspections?

11 DR. GORNY: I really couldn't say what the
12 model would look like at this point, but it certainly
13 probably needs cooperation from state government as
14 well.

15 MR. LANDA: Ms. McGarry.

16 MS. MCGARRY: One of your comments you
17 mentioned that there's in the spinach outbreak, one
18 ranch with basically the outbreak strain. What are your
19 thoughts about the fact that there are other ranches
20 that had the 0157 but not the outbreak strain and what
21 that means for (inaudible)

22 DR. GORNY: It's my understanding that there