

1 tell us there can be no such thing as zero risk and we
2 have no cooking step for our product, the public must
3 be able to trust in a independent, objective
4 government body as the ultimate arbiter of what is
5 safe enough. It is also FDA's responsibility to
6 ensure that industry is complying with these
7 standards.

8 Now, that doesn't mean that FDA needs to
9 hire 5,000 inspectors to travel to every farm in the
10 country or around the world, but it does mean that FDA
11 must have relationships with other country
12 governments, USDA, state agriculture and regulatory
13 officials to ensure that compliance is taking place.
14 Cooperative agreements between FDA and the states have
15 been extremely effective in providing oversight of
16 food safety standards.

17 Third, we believe produce safety standards
18 must allow for commodity-specific food safety
19 practices, best of the best available science. In a
20 highly diverse industry that is more aptly described
21 as hundreds of different commodity industries, one
22 size clearly does not fit all.

1 In "The Federal Register Notice" announcing
2 this hearing, FDA confirms that five produce
3 commodities, only five, have been associated with
4 80 percent of all foodborne disease outbreaks
5 associated with produce in the past 10 years. That is
6 where we must direct our resources.

7 Let me now talk specifically about several
8 regulatory options for FDA. First, we support the
9 approach taken by FDA to establish the broad GAPs and
10 GMPs applicable to all producers at farm level.

11 The 1999 guidance document continues to
12 provide an effective roadmap for producers and
13 cooperative agreements with USDA and the states could
14 assure greater compliance with these guidelines based
15 on today's science and as they are modified by FDA in
16 the future to reflect increasing knowledge.

17 These guidelines can truly minimize risk
18 when well understood and implemented by growers and
19 packers. The need for greater implementation of GAPs
20 calls for a well-funded, intergovernmental effort
21 between FDA, USDA, the states, and industry to educate
22 producers across the country and internationally.

1 Second, we support FDA's approach to develop
2 commodity-specific GAPs where there is a demonstrated
3 need. This must be a scientific process looking at
4 outbreak history and potential risk factors to ensure
5 that resources are not diluted, trying to address
6 hundreds of commodities that have never been linked to
7 illness.

8 Today, FDA has published commodity-specific
9 GAPs only for fresh sprouts. Alternatively, the
10 Agency has asked the industry to develop
11 commodity-specific GAPs for leafy greens, tomatoes,
12 melons, green onions, and herbs.

13 We have taken this challenge seriously and
14 worked diligently to bring scientists from academia,
15 government, and industry together in formulating these
16 best practice documents.

17 But we believe it is important that the FDA
18 now pursue this regulatory model used with fresh
19 sprouts and publish its own commodity-specific GAPs
20 where warranted rather than simply provide technical
21 input to industry-prepared documents.

22 FDA must endorse, embrace, and defend these

1 standards as sufficient to allow public confidence in
2 the safety of the food supply based on the best
3 science available. Now, don't underestimate the power
4 of FDA-published, commodity-specific guidance. Let me
5 quote from the sprout guidance document:

6 "The following recommendations identify the
7 preventive controls that the FDA believes should be
8 taken immediately to reduce the risk of raw sprouts
9 serving as a vehicle for foodborne illness and ensure
10 sprouts are not adulterated under the food safety
11 provisions of the Food, Drug & Cosmetic Act. Failure
12 to adopt effective preventive controls can be
13 considered insanitary, conditions which may render
14 food injurious to health."

15 Producers of fresh sprouts do not consider
16 this voluntary guidance or an option that they may
17 choose or not choose to follow. We believe the same
18 approach should be taken with specific commodity
19 groups in which FDA determines there is a specific
20 preventive control necessary for food safety.

21 I would also add that FDA's administrative
22 process of public notice and comment on draft and

1 final guidance offers the most equitable way to
2 receive broad input on such standards from industry as
3 well as all other stakeholders.

4 Finally, we strongly support FDA's approach
5 to address specific standards for fresh-cut processing
6 as contained in the Agency's "Guide to Minimize
7 Microbial Food Safety Hazards of Fresh-Cut Fruits and
8 Vegetables published just last month in its final
9 version.

10 We strongly support HACCP food safety
11 programs in all fresh-cut processing plants. Although
12 research has not yet identified a kill step such as
13 pasteurization for fresh-cut, ready-to-eat produce, we
14 must apply strict processing controls to minimize any
15 risk that might be introduced from incoming raw
16 agricultural product or at the processing level.

17 Again, consider the legal power of this as a
18 guidance document. FDA has provided its
19 interpretation of what is required to comply with
20 mandatory GMPs to which all fresh-cut processors must
21 adhere. This carries serious liability both in
22 terms of government inspection of fresh-cut processing

1 plants and product liability.

2 Let me conclude with a few comments about
3 funding and spending priorities. We believe one of
4 the most critical issues at this hearing is whether
5 FDA is adequately funded, has sufficient staff with
6 scientific training and experience in our sector of
7 the food industry, has research dollars available to
8 address key questions, has strong working agreements
9 with the states to provide support in the field, and
10 has the commitment of the administration and the
11 Congress.

12 We believe those criteria are essential to
13 have a strong, effective federal regulatory framework
14 for the produce industry. In the past several months,
15 I have testified at both House and Senate
16 appropriations' hearings in support of increased
17 funding for FDA for both senior scientific staff and
18 research in the area of produce safety.

19 Our industry is doing everything today we
20 know to reduce the risk of foodborne disease, but
21 there are many scientific questions literally begging
22 for research.

1 We need better understanding of ways to
2 reduce E. coli in cattle. We need better ways to
3 prevent potential contamination from pathogens that
4 might be present in the natural environment. We need
5 to develop more effective microbial reduction and
6 elimination techniques after harvest and in
7 processing.

8 While there is no obvious kill step around
9 the corner, developing such a step as pasteurization
10 while still protecting the natural texture and flavor
11 of our product would be a critical advancement in
12 preventing even rare foodborne illness.

13 In conclusion let me return to the important
14 role fresh fruits and vegetables play in public
15 health. With the public health imperative to increase
16 our consumption of fruits and vegetables, we simply
17 cannot allow fear of food safety to become linked with
18 these healthy foods.

19 We as an industry must do all we can to
20 prevent illness from ever occurring, and we will. At
21 the same time we pledge to support a strong federal
22 food safety regulatory framework that assures the

1 public that appropriate safety standards are in place
2 and are being met by the industry.

3 Thank you.

4 (Applause.)

5 MR. BARRETT: Thank you, Mr. Stenzel.

6 Next, Mr. Bryan Silbermann from PMA.

7 MR. SILBERMANN: Thank you very much, Bob.
8 Thank you for this opportunity.

9 Good morning everybody. Let me tell you
10 that it is not just the members of the Produce
11 Marketing Association and the United Fresh Produce
12 Association who benefit from us working together and
13 avoiding duplication.

14 Tom and I have worked closely to make sure
15 that what I say is not going to duplicate necessarily
16 everything that he says. Let me start off by saying
17 that a lot of what he says I agree with 110 percent.
18 Thank you, Tom, for that. I also want to acknowledge
19 my colleague Kathy Means, who is known to many of you
20 here at FDA.

21 PMA is the largest association representing
22 the fresh produce marketers worldwide across the

1 entire supply chain. As Dr. Brackett said, that is
2 everybody from growers and shippers through the retail
3 chain, some of whom are represented here, as well as
4 other associations, restaurant chains and the like.

5 This unique supply chain orientation gives
6 us the benefit of what we like to call a 360-degree
7 view of the world of produce. Also, let me tell you
8 my personal belief. As chairman of the Partnership of
9 Food Safety Education, which involves federal agencies
10 including FDA and CDC as well as food industry and
11 consumer groups, some of whom are here today.

12 I am personally committed to ensuring that
13 we always view produce safety as a continuum that
14 stretches from the farm to the dining table. I thank
15 FDA and specifically CFSAN for convening these
16 hearings to address produce safety.

17 We applaud the Agency for its commitment to
18 food safety for the new fresh-cut produce guidance and
19 all the other efforts, both well known as well as not
20 so well known. These all contribute to fresh-produce
21 safety. Later, I will comment on specific steps where
22 we should consider doing even more together.

1 Michelle Smith, thank you very much for also
2 drawing attention to the fact that it is both the
3 focus on increasing consumption as well as on produce
4 safety that is important to CFSAN. Let us never
5 forget that.

6 September 14, last year, was not the
7 beginning of the produce industry's commitment to food
8 safety. That commitment started generations ago with
9 American farmers whose tradition of excellence forms
10 the very foundation of today's highly sophisticated
11 produce industry.

12 We also recognize that the growth and
13 complex nature of the produce supply chain in recent
14 decades demands that we approach food safety as a
15 collective responsibility.

16 Industry has spent tens of millions of
17 dollars to employ the best and most recent scientific
18 knowledge to protect our products and to protect our
19 customers. Protecting our customers is paramount.

20 We have demonstrated commitment to good
21 agricultural practices on farms, good manufacturing
22 practices in processing plants, and ongoing education

1 for food handlers as well as the public.

2 PMA's latest member survey just conducted
3 last month makes it abundantly clear once again
4 consumer confidence in our products remains as fragile
5 as the tender leaves of the freshest salads.

6 We never, never take nor have we taken that
7 confidence for granted because doing so would be
8 irresponsible to the public and harmful to our own
9 livelihoods. We have a vested interest in doing what
10 is right every bite and every time.

11 PMA has helped other associations and FDA
12 develop the industry precursor to the good
13 agricultural practices that, as you heard, have been
14 in place since 1998.

15 We have prepared our members through
16 training and education so that they would have robust
17 food-safety programs. We have collaborated with the
18 folks right here at CFSAN for a long time. I'm
19 delighted to see my good friend, I won't say "old
20 friend," Fred Shank a little while ago.

21 We have participated in industry coalitions
22 including the one formed with UFPA in the summer of

1 2004 to address the development of commodity-specific
2 produce guidance together with FDA.

3 Working with the Canadian Produce Marketing
4 Association, PMA has been at the forefront of adopting
5 information technology that facilitates rapid
6 tracebacks including a pilot program and a
7 best-practices document.

8 Our efforts have not been limited just to
9 industry. Through the partnership of food safety
10 education that I mentioned earlier, two years ago we
11 funded guidelines to help consumers handle fresh
12 produce safety.

13 FDA is an important collaborator in the
14 partnership and we welcome and encourage your support
15 for its ongoing education efforts. Industry and
16 government must do their part to deliver safe,
17 nutritious fruits and vegetables, and consumers have a
18 role to play in this, too.

19 We also regularly track consumer confidence
20 in fresh produce nationwide through ongoing research.
21 We take our role as an industry leader seriously. We
22 are committed to doing whatever it takes to protect

1 public health and rebuild consumer confidence in the
2 delicious healthful products our members grow and
3 market. I know this is a goal FDA shares.

4 Let me now turn to what we have done in
5 recent months and what is being planned, particularly
6 in the areas of research and training. We have just
7 committed two and three-quarter million dollars in
8 additional resources to food safety.

9 Two days ago, at the University of
10 California at Davis, I joined California Secretary of
11 Agriculture A.G. Kawamura as we launched the new
12 Center for Produce Safety at Davis under the umbrella
13 of the Western Institute for Food Safety and Security
14 aimed at coordinating, funding, and disseminating
15 research to enhance the safety of fresh produce
16 worldwide.

17 The center will bring together experts from
18 industry, government, and academia to find answers to
19 how it is that our products get contaminated, and,
20 even more importantly, what we can do to stop that.

21 I am delighted that we were joined by
22 officials from federal and state government at this

1 launch including FDA and the California Department of
2 Health Services.

3 PMA has committed \$2 million specifically to
4 help launch the Center for Produce Safety, and I fully
5 expect that PMA will provide more as we see results.
6 Those funds have already been matched with another
7 \$2 million from one industry company, and we expect
8 more to follow.

9 The State of California committed another
10 half million dollars. I know that FDA is working to
11 strengthen its ties with the Western Institute at U.C.
12 Davis.

13 I urge the Agency to look very closely at
14 these commitments from industry, from the State of
15 California, and the university and to do everything
16 FDA can to support this critical effort to improve the
17 understanding of produce safety and to supply answers
18 to critical questions, some of which have already been
19 raised here this morning.

20 This deserves your active involvement and
21 your strongest support. Let me be very clear about
22 the goal of the Center for Produce Safety. We intend

1 to create nothing less than a world-class center of
2 excellence for produce safety research and training
3 outreach applicable far beyond the borders of
4 California.

5 I know I also speak for the leadership of
6 the University of California and our membership in
7 committing to that goal. We are also committing funds
8 for enhanced education and training for all parts of
9 the supply chain in conjunction with other
10 organizations including Western Growers Association
11 and the California Farm Bureau Federation.

12 We will be spending at least \$200,000 in
13 this effort, and these will be coordinated through the
14 new center. We applaud the work of other
15 organizations including the successful effort to
16 establish a California Lettuce and Leafy Greens
17 Marketing Agreement, founded on strong science-based
18 food safety protocols and state verification.

19 In addition to these efforts I have just
20 outlined, let me offer the following recommendations
21 to CFSAN. No one can be everywhere at all times.
22 Food safety efforts have to be prioritized based on

1 risk. You've heard this several times. FDA has
2 identified those commodities most likely to be
3 associated with outbreaks, and efforts should be
4 focused there.

5 As I said, we applaud California's efforts
6 to create a marketing agreement for lettuce and leafy
7 greens, and we believe that those efforts as well as a
8 host of others are all-important components to
9 enhanced produce safety.

10 We believe that the initiative in California
11 needs to be followed by a robust federal effort that
12 is verifiable and applies to any products grown in the
13 United States or abroad.

14 We need to promote public confidence and
15 avoid a "patchwork" approach to an issue that is
16 crying out for an umbrella solution, and yet under
17 that umbrella we should have commodity-specific
18 protocols based on sound science and prioritized by
19 risk.

20 I mentioned traceability earlier. At a
21 session I moderated at PMA's annual meeting last
22 October, Dr. Brackett noted that traceability is the

1 one biggest improvement he would like to see from our
2 industry.

3 We suggest that FDA joins with the experts
4 from association staff and membership to better define
5 the very specific needs for traceability that are not
6 currently being met by industry practices.

7 We have a strong foundation in the work
8 already done in the United States and Canada to define
9 best practices. We want to work hand in hand with FDA
10 to target what it is that industry can do better the
11 meet the Agency's needs and expectations moving
12 forward.

13 We share the same goal with FDA, creating
14 the tool so industry can quickly help narrow the scope
15 of any future outbreak. Another shared goal we have
16 is public health. We welcome the opportunity to work
17 with FDA to improve communications.

18 We must assure that the public has all the
19 information required to take appropriate action by
20 being as specific as possible as early as possible in
21 the event a public health risk is identified.

22 Rapidly narrowing the focus of an

1 investigation is responsible to public health and
2 mitigates damage to those in the affected industry
3 that are not implicated and should not be implicated
4 in an outbreak.

5 Again, thank you very much for this
6 opportunity to speak here today. I'm happy to answer
7 any questions you may have.

8 (Applause.)

9 DR. BRACKETT: Thank you, Mr. Silbermann.

10 We will next hear from a representative of
11 consumer interests, and this will be by Ms. Caroline
12 Smith-DeWall, and she is the director of the Food
13 Safety Program at the Center for Science in the Public
14 Interest and also the coauthor of "Is Our Food Safe:
15 A Consumer's Guide to Protecting Your Health and the
16 Environment."

17 Ms. DeWaal is the leading consumer analyst
18 on reform of laws and regulations governing food
19 safety. Ever since 1999, she has maintained an
20 annually published listing of foodborne illness
21 outbreaks organized by Food Source that now contains
22 15 years of worth of outbreak data.

1 CONSUMER PERSPECTIVE

2 (PowerPoint presentation in progress.)

3 MS. SMITH-DEWAAL: Good morning. I
4 represent the Center for Science in the Public
5 Interest. We have over 900,000 consumer members. We
6 publish a newsletter called Nutrition Action Health
7 Letter to communicate with our members.

8 We are one of the big promoters of eating
9 your fruits and vegetables. Despite my talk today and
10 what I'm about to tell you, I want you to know that
11 CSPI wants you to eat your fruits and vegetables.

12 I'm going to cover a number of issues here.
13 The key issue is declining consumer confidence. I've
14 never been to a hearing like this where there is
15 literally so much agreement between the industry and
16 the consumer panels right off the bat, because the
17 problem impacts us all. We don't want consumers to
18 fear their lettuce. We want them to be eating their
19 lettuce, so this is a critical issue.

20 We are going to talk about the produce
21 outbreak trends. Art Liang covered a lot of it, but
22 I'm going to show you very visually what this means

1 and how it is impacting, what the real trends look
2 like, the failure of the voluntary guidelines and then
3 the roadmap to the future.

4 These outbreaks were very, very clear but
5 consumers didn't know that the hazards in their
6 produce could be as serious as the hazards in their
7 meet.

8 This was a Rutgers University telephone
9 survey that basically documented the impact for months
10 afterwards of the outbreak and the public messages
11 around it.

12 It is critical, though, that FDA get out the
13 information it knows in an outbreak situation in order
14 to prevent people from continuing to eat the products,
15 get sick, and potentially face life-threatening
16 illnesses. Communication is critical and early
17 communication, which happened in this case, was very
18 important.

19 Here are the trends we've been watching.
20 Our outbreak data covers 15 years and is largely
21 composed of outbreaks collected by the Centers for
22 Disease Control and Prevention; although, some of the

1 earlier outbreaks we also got from articles.

2 Art talked about the change in the outbreak
3 data in 1998, which is reflected in our slides. This
4 shows you the same slide on produce, but it also shows
5 you what we are looking at -- because we track all
6 food products, all major food categories, not just
7 produce -- what it looks like with respect to seafood,
8 beef, and poultry.

9 The big news, and we were getting this out
10 as CDC was as well, was that produce is becoming
11 probably the major contributor to outbreaks and
12 illnesses in the U.S.

13 The blue line that is above the produce
14 outbreaks indicates how many people are getting sick
15 from outbreaks per year. You can see that while
16 seafood also has a lot of reported outbreaks, the
17 cases are much lower, the number of cases, and beef
18 and poultry we monitor as well.

19 The trends there are also worth watching,
20 but produce is clearly making a lot of people sick,
21 and this is why. The size of each outbreak is in fact
22 significantly larger when it comes to produce than

1 other commodities. Here are the pathogens.

2 Farida Bhuiya is my epidemiologist trained
3 at Emory. Thank you, Farida, for putting this
4 together.

5 This shows the pathogens. We divided it out
6 by vegetables, fruits, and produce dishes. Norovirus
7 constitutes about 40 percent of the produce outbreaks.
8 Art really described the importance of having the
9 human pathogens controlled as well as the animal
10 pathogens.

11 Salmonella is second, and E. coli comes in
12 at different points on the different lists. But the
13 bottom line is when we have analyzed the data,
14 human-transferred pathogens constitute about
15 40 percent of the outbreaks. Salmonella and E. coli
16 together constitute about 25 percent of the outbreaks.
17 These are both significant things that need to be
18 controlled.

19 Here are major product outbreaks linked to
20 imports. Back in 1996-97, we really became aware of
21 this with both the cyclospora in raspberry outbreaks,
22 those coming from Guatemala, and then also an outbreak

1 of Hepatitis A in a school system which caused some
2 pretty severe illnesses.

3 These have continued, though. The outbreaks
4 from cantaloupe from Mexico has resulted in at least
5 one death, and then in 2003 we had the major outbreak
6 linked to Chi-Chi's. That one outbreak from a single
7 restaurant, over 500 people became ill. I think the
8 numbers were really topping 600, and three people
9 died.

10 What is really significant to me in that
11 outbreak is that the same scallions had also caused
12 three other outbreaks I think in three other states,
13 but they weren't caught; they weren't tracked. No
14 public notice was made in that case. Chi-Chi's
15 unknowingly went forward and purchased the green
16 onions that caused that outbreak.

17 I was very critical of the Agency at that
18 point, which I wasn't with respect to their
19 announcement on spinach. The spinach outbreak was not
20 our first produce outbreak in '06. In fact, I'm
21 probably missing a few here, but the slide was too
22 small.

1 In June, we had a lettuce outbreak from
2 another strain, hazardous strain, of E. coli, then in
3 September, we had both the spinach outbreak and an
4 outbreak of tomatoes with salmonella. Unfortunately,
5 CDC didn't even notice the tomato outbreak until it
6 was all over. In November and December, we had the
7 Taco John's and Taco Bell outbreaks, one in the
8 Midwest and the other in the Northeast.

9 We have been very concerned the FDA's
10 guidelines are not mandatory. We think if there are
11 food safety steps the industry needs to take they need
12 to take them. This isn't rocket science. The growers
13 know this probably better than we do. But if there
14 are steps that can protect your customers, you need to
15 do them.

16 The guidelines, the GAPs, were published in
17 1998. In 2004, FDA noticed, or I'm sure they did in
18 advance, but they sent a letter to lettuce and tomato
19 growers saying, "Guys, listen up, you're not following
20 the rules or the guides," and asked people to review
21 their guidelines. FDA has made a lot of noise to the
22 industry and a lot of requests.

1 Very significantly, a Cornell study I
2 believe in 2004, and Robert Gravani can correct me
3 when he gets up here, found that one-third of the
4 New York State producers were unaware of the GAPs for
5 their crops in that year. Really, the message, I know
6 you guys are trying to do education but the messages
7 aren't sinking in.

8 CSPI had petitioned both the State of
9 California in October and FDA in November following
10 the spinach outbreak. As I said, we had been aware of
11 these trends. We were waiting for this event. Once
12 it happened, I felt we had to move very quickly.

13 I think the key here and I think what we are
14 hearing from industry, too, is ensuring that consumer
15 confidence is not further eroded is critically
16 important right now. Moving quickly is very
17 important.

18 What I am proposing to FDA is that they
19 follow a model they have followed before with a
20 similarly situated industry. In the early 1990s,
21 there was a lot of news and information and
22 congressional interest in seafood safety.

1 Now, the seafood industry is made up of a
2 lot of small players, a lot of small business people
3 maybe with a boat and some also very large ones, but
4 FDA at that point implemented the first HACCP
5 regulation for use in the industry. There had been a
6 much more prescriptive approach used for low-acid can
7 food, but this was the first of the modern HACCP
8 rules.

9 For the produce industry, we think this is a
10 great model. It requires that the growers or
11 processors develop a food safety plan that you write
12 down what you already know and what you are doing to
13 protect the safety of the products; that FDA should
14 set requirements for what should be in the plan based
15 on the evidence from the outbreak data; and that in
16 order to establish the metrics and the science, to
17 bring the science in, that they use another tool that
18 they used with the seafood industry.

19 Now, remember seafood is a very diverse
20 products: It's oysters, it's salmons, it's octopus,
21 and calamari. Each of these has unique hazards. In
22 fact, there are about 300 different species of seafood

1 and the hazards range -- I love seafood, sorry -- it's
2 ciguatera, we have ciguatera, which is a chemical
3 toxin; scombroid poisoning; vibrios. There are some
4 very cool hazards that arise in seafood.

5 (General laughter.)

6 MS. SMITH-DeWAAL: They are all different.
7 Sorry, no one invites me to dinner because I like this
8 stuff. They are all different; they are all unique.
9 This is also true for the produce industry. What they
10 did in that case is they published a hazards and
11 controls guide, "If you are fishing for tuna, here are
12 the hazards you need to be concerned about," which
13 happens to be in part scombroid. "These are the
14 controls you need to use, which are temperature abuse
15 or controls from temperature abuse." These are pretty
16 straightforward, and it is a really good model to use
17 in this case.

18 CSPI has petitioned the Food and Drug
19 Administration already, and we are considering
20 petitioning them again. We would like your support
21 for moving forward with a petition.

22 FDA should require all growers to have a

1 written food safety plan that is specific to the
2 environmental conditions on the farm. This is
3 designed by the grower, the farmer, themselves.

4 They should develop uniform standards for
5 evaluating the plans for things like water quality,
6 manure use and management, and worker sanitation, and
7 that the written plan should be audited once per
8 growing season either by FDA or FDA should review
9 state or third-party audits of written plans.

10 Now, this is a radical suggestion. The
11 audits, we understand the FDA cannot hire an army of
12 on-farm inspectors. It wouldn't be a great use of
13 federal resource, frankly, when there are other people
14 who can probably do this job.

15 The audits, FDA should utilize state
16 programs, if the states can do it, but the second
17 place is produce buyers. We rely on the Safeways and
18 the Giants and the Wal-Mart's and the Costcos to
19 actually send auditors out to check the quality of the
20 products. We think that army of people can be
21 utilized to help implement this program.

22 What everyone is crying for is consistent,

1 uniformed standards. The standards should cover the
2 application of manure and animal waste. These
3 standards are already utilized in the organic
4 industry. If you are a certified-organic grower, you
5 already must comply with standards for the use of
6 manure.

7 Water for assessing both the microbial and
8 chemical quality water. Hygiene, as I mentioned,
9 40 percent of the outbreaks are traced to human
10 pathogens.

11 While those can enter at any point, they
12 could enter on the farm. They could enter in the
13 kitchen. Yeah, we want to make sure farm workers are
14 using good hand washing and sanitation facilities.

15 Also, the processing plants are clearly not
16 going to be forgotten in this process. We should have
17 standards, sanitation standards, and good
18 manufacturing practices for the processors.

19 Finally, the issue of traceback is
20 critically important. When mistakes occur, it does
21 help the industry if people can identify the product
22 quickly and narrow the scope of the recall. That

1 helps everyone involved. It doesn't mean FDA should
2 wait to make an announcement. If the products are
3 marked adequately, then the announcement will be more
4 narrow.

5 My final point is that none of this can be
6 done without resources. FDA lacks the staff and
7 resources to function effectively. The food program
8 and the inspection program has been declining.

9 Really, when you look at it, the Food and
10 Drug Administration regulates about 80 percent of the
11 food supply, but they do it on a shoestring budget.
12 With the recent 2008 budget, FDA was only given
13 \$10 million in additional funding, and it hasn't been
14 approved by Congress yet, to deal with these issues.
15 That's no where near enough.

16 USDA in contrast was given about 10 times
17 that amount, \$104 million for meat and poultry
18 inspection, which is also needed in that area because
19 they have been facing significant vacancies, but FDA
20 needs to be more on par with that agency. We need to
21 be looking at hundreds of millions of dollars in this
22 program rather than \$10 million.

1 Just one final note on the budget because
2 I've watched these things in Washington. The U.S.
3 Department of Agriculture was also given \$164 million
4 in new money for the Food and Agriculture Defense
5 Initiative. Well, gosh, we want our food safe and we
6 want it protected, but FDA has a huge responsibility
7 here, and it wasn't given any of that money.

8 Thank you. Here is the information. You
9 are welcome to contact us to get more from our
10 outbreak database. We respond to email requests all
11 the time.

12 Thank you.

13 (Applause.)

14 DR. BRACKETT: Thank you, Ms. DeWaal.

15 Our final panel member this morning speaking
16 is going to talk on behalf of the research needs, and
17 this is Dr. Martha Roberts, who is now with the
18 Institute of Food and Agricultural Science, or "IFAS,"
19 at the University of Florida.

20 She is the former deputy commissioner of
21 agriculture for the State of Florida from 1991 to 2003
22 in the Florida Department of Agriculture and Consumer

1 Services and assistant commissioner of agriculture,
2 which she happened to be the first woman in the U.S.
3 to do that.

4 From 1984 to 1991, she has served on
5 numerous food safety committees and is known quite
6 well to the food safety community, and so we are
7 pleased to have her here as well.

8 SCIENCE/RESEARCH

9 (PowerPoint presentation in progress.)

10 DR. ROBERTS: Hello. I'm very glad to be
11 speaking with you today and to be a part of this
12 wonderful public meeting and public hearing, and I
13 commend FDA for this.

14 I'm going to be speaking to you today and
15 covering the subject of the state of science. Now,
16 quite frankly, I can sum it very easily in that there
17 is a huge body of scientific information out there,
18 but the current science is inadequate to address all
19 of the questions on media, production, processing, and
20 handling.

21 I think you have already arrived at this
22 conclusion yourself from some of the comments of the

1 earlier speakers. However, I think you would be
2 surprised to see the vast amount of applicable science
3 that has been published that we don't as yet have
4 transferred into everyday practices.

5 You cannot talk about present science
6 without talking about future science, and so some of
7 these comments relative to future needs will be
8 blended into the presentation.

9 But we certainly have a critical need for
10 integrated, concentrated, and a multidisciplinary
11 approach to ferret out the best practices that are not
12 currently incorporated by the industry and not
13 currently founded on sound scientific studies.

14 We need to strengthen this coordination
15 among our researchers nationwide, worldwide and the
16 communication that we have between all of our
17 regulators, researchers, and industry on what
18 available science is out there.

19 There is a tremendous amount of industry
20 science that is not available generally to the
21 regulators and to the general public that is working
22 with individual companies. To have more than industry

1 data available, would be excellent.

2 Now, we have multiple difficulties with
3 current science. Quite frankly, none of the
4 researchers want to publish any negative data. They
5 accumulate negative data, and they put it aside and
6 never mention it, but it is extremely valuable if you
7 are out there in the regulated community.

8 Survey work is sometimes look down your
9 nose, if you're involved in a survey, but it is very,
10 very valuable to have this information available to
11 you and we must find some way of publicizing this. We
12 currently have great difficulty in funding applied
13 research or any of this survey work. Regrettably,
14 many scientists love science and do not love writing.

15 (General laughter.)

16 DR. ROBERTS: We know of multiple
17 scientists, right now I know of one scientist who has
18 enough data for 10 publications on the food safety of
19 tomatoes. It's extremely needed information. They
20 won't release it in detail, of course, until it's
21 published in a peer reviewed journal, but we have to
22 have some way to speed up the availability of this

1 science to us.

2 Duplication, I hate to mention this, but we
3 don't have enough money to fund the science that's
4 needed now and we certainly don't need people in
5 multiple universities conducting the same study. It's
6 sort of wasted time and effort.

7 We need sufficient science to confirm the
8 validity of the science, but we do not need, as
9 Dr. Buchanan said at one of our last meetings, 20 more
10 papers on the effects of chlorine. Any efforts that
11 we can have to have more coordination and
12 communication back and forth between our scientific
13 communities is well put.

14 Regrettably, I hate to tell you that the
15 metrics we are developing, and I think everyone will
16 recognize it here, are not based on sound science
17 related to produce.

18 They may be based on sound science related
19 to water standards, but we don't have the studies to
20 document that these are the metrics that we need for
21 produce. There is a really critical need there.

22 These are just some of the dilemmas. I

1 don't have the solutions, but there needs to be a lot
2 of close examination to see if some of the scientific
3 studies that have been done on lettuce, for instance,
4 have particular applicability to tomatoes or to
5 melons. We have not had that critical review.

6 There is a huge body of science out there,
7 over 60 years. But just as we were talking about
8 FDA's budget compared to USDA's, there has been a
9 minuscule amount of money devoted to produce safety
10 research compared to animal research. There has been
11 very limited research on the farms and the actual
12 production areas. I think we all agree that this is
13 needed.

14 The interpretive reviews of science status
15 is desperately needed. As to whether FDA can play
16 that role, we need someone to gather together an
17 august body of scientists to critically review the
18 science that's out there. The goal of everyone is the
19 prevention of the illness and contamination. As yet,
20 we don't have a complete science to support that.

21 There are many produce safety areas that are
22 being discussed and studies being done now, but we

1 don't have all of the disciplines integrated together.
2 As you all know, the whole produce safety area
3 involves very complex questions with diverse crops,
4 widespread geographical areas, extreme low levels, and
5 environmental contamination.

6 As yet, I have not been able to find very
7 many people in this country who are extremely versed
8 in certain disciplines that we need involved such as
9 microbial ecology of salmonella and some of the other
10 pathogens we're dealing with, and the geneticists need
11 to be involved.

12 We have multiple pathogens. As you know,
13 there is something that is causing there to be very
14 geographical distinctions between these, and we don't
15 know scientifically and there are no studies out there
16 to show this.

17 Most of the research conducted in the past
18 and being conducted at the moment is concentrating on
19 the contamination focus. Everything from the farms to
20 the farms, packing houses. We have a lot of research
21 that has been devoted to good agricultural practices,
22 trying to show what practices can be effective to

1 prevent contamination from feces, irrigation waters,
2 soil amendments, et cetera.

3 We have a whole host of research papers on
4 internalization of pathogens, and none of it is
5 conclusive. Quite frankly, some of the research areas
6 that are most critical to produce safety are not
7 involved in produce safety at all, and that is the
8 real need for continued research and more definitive
9 review of what is out there on microbial methods of
10 analysis.

11 If you are trying to investigate a foodborne
12 outbreak, or if you are trying to confirm whether or
13 not a foodborne outbreak is there, you cannot be using
14 an analytical method that's going to take you three to
15 ten days for confirmation.

16 The whole collaborative process with
17 acceptance of methods by the Food and Drug
18 Administration through the AOAC collaborative process
19 or through some other collaborative process, we have
20 to have a great deal more rapid methods which are
21 accepted by the regulatory community.

22 Again, we have found a great deal of science

1 out there on kill steps, but basically there is no
2 magic bullet. The difficulty most prominently, as
3 shown in the last two lines, is that we have a huge
4 body of research that is being done on various
5 antimicrobial compounds, none of which are registered
6 for use on produce. We have to have the cooperation
7 of EPA and with rapid approval with what science is
8 showing could be very effective agents.

9 I want to go over a little bit about what
10 we've done on science in the area of tomatoes on the
11 East Coast with just a brief mention of two meetings,
12 because it brings up some excellent work that
13 Dr. Buchanan and Gendall have done.

14 Back on November 30th, down in Orlando, we
15 worked cooperatively with FDA to pull together all of
16 the researchers, industry, and regulators in the seven
17 East Coast states that were involved in the growing of
18 fresh tomatoes and tried to invite them to at least
19 start and increase the coordination and cooperative
20 effort between all of these scientists.

21 All of these documents are availability on
22 the website shown there, which is a research website

1 for the University of Florida.

2 As a part of this, you have already had a
3 presentation by Dr. Marion Aller, the three things
4 that came out of this meeting were the researchers and
5 the industry said that there was a real critical need
6 to continue to review science but to establish
7 priorities for the research that was needed to fill
8 these data gaps; we requested of AFDO assistance in
9 development of the model; and promised more rapid
10 communications.

11 Well, out of this Dr. Buchanan and Gendall
12 presented an excellent bibliography of all of the
13 scientific papers that had applicability to the whole
14 problem of tomato food safety.

15 Dr. Buchanan, I'll call your attention to
16 one of the presentations on that website where he
17 actually went through all of the individual papers and
18 picked out the nugget of most applicability to the
19 problem and did an excellent review.

20 Some of the papers went back into the
21 seventies and eighties, as you will see here, just
22 challenging some of the common beliefs, for instance,

1 that tomatoes are an acidic food and don't support the
2 growth of foodborne pathogens.

3 Well, here are a whole host of papers that
4 show the opposite -- some of which, as you will see,
5 even authored by our illustrious chairman of this
6 hearing today.

7 Even going into some of the papers in 2003
8 by Beuchat and 2006. There was an excellent review of
9 this scientific information, again, looking at the
10 antimicrobial treatments in this specific instance for
11 tomatoes, but going through some of the published
12 scientific information available for those individual
13 treatments, and showing very definitely how they could
14 be utilized. I call your attention to that
15 bibliography.

16 Some of the evidence and some of the
17 scientific studies, though limited, was on production
18 but the body of science here is very limited. As a
19 followup to that, one of the requirements that
20 everyone challenges us with was to try to bring all
21 the researchers together to establish a priority of
22 the data gaps.

1 We were very pleased at the university to
2 cosponsor this with the Joint Institute of Food Safety
3 and Applied Nutrition, just in late February, where
4 40 different scientists from around the country from
5 coast to coast were invited to come in to look at all
6 the data gaps that had been identified by FDA and CDC
7 and try to prioritize those as to what was needed and
8 to begin the process of an ongoing platform of
9 communication with these scientists.

10 Again, if you want to look at all these
11 papers and the comments there, go the JIFSAN website
12 or either go to the University of Florida research
13 website, and it will have a link to that.

14 These were the priorities as far as the food
15 science needs for tomatoes. The difficulty is there
16 are 12 or 15 categories here -- no money, no funding.
17 The requirement is, as you well know, to get a
18 congressional appropriation, a minimum of a year or
19 two or to go through a competitive grant process. We
20 are in desperately desperate need of funding, but this
21 is what the scientists told us were the real needs.

22 Are there alternative processing

1 technologies, particularly dry processing systems that
2 can be used to either reduce the presence or spread of
3 microbial contamination? Are there specific seasons
4 or microclimates or weather events associated with
5 contamination of tomatoes in the field?

6 You could likewise expand that to lettuce or
7 any other produce. What vectors and vehicles are
8 important in transmitting pathogens? What is the
9 relative importance of this internalization question
10 versus surface contamination?

11 Are there specific microbial serotypes or
12 genotypes associated with tomatoes or associated with
13 onions or associated with lettuce? Are there specific
14 varieties of a particular produce that more likely to
15 carry the pathogens? Then, are there effective
16 approaches that can be used to activate internalized
17 pathogens? This goes on.

18 Basically, we found that there is a
19 tremendous amount of work ongoing in many of the
20 universities involving multiple departments. I'm
21 delighted that I've even found a microbial geneticist
22 who is doing a whole genetic microarray of the genes

1 in every salmonella that may have some effect or tie
2 with salmonella in tomatoes. It's an unbelievable,
3 exciting field, but the summary is the current science
4 is expanding, but it's inadequate.

5 We call for a critical review and for some
6 long-term thinking, and we would hope that FDA can
7 have this leadership to provide an overview and an
8 in-depth review of the science that is there.

9 Thank you very much.

10 (Applause.)

11 DR. BARRETT: Thank you, Dr. Roberts.

12 Again, we will have our FDA Panel questions
13 with the same rules as before. I will start off with
14 Dr. Steve Solomon.

15 QUESTIONS FROM FDA PANEL

16 DR. SOLOMON: Mr. Stenzel, I will address
17 this to you. You talked about the need for oversight
18 over the industry and you talk about the mechanisms
19 doing that domestically. You talked about cooperative
20 agreements with USDA, and you talked about agreements
21 with the states. I would like your thoughts more on
22 how that could be done on product grown overseas and

1 imported.

2 MR. STENZEL: Dr. Solomon, I think on the
3 international front probably the best model we can
4 look at is what you've done with cantaloupes from
5 Mexico.

6 You basically have to move into a
7 cooperative relationship with the foreign government
8 in order to make sure that the production from that
9 particular country is meeting a similar set of
10 criteria.

11 In some sense, there is a very tough
12 restriction on imports of melons because of that.
13 Again, it is a cooperative type relationship that I
14 think FDA has to adopt with those governments.

15 As far as actual verification and
16 compliance, some of the same mechanisms that we have
17 talked about in the U.S., government doing audits or
18 perhaps even third-party, independent auditors, but
19 auditing to a standard that FDA sets in conjunction
20 with that foreign government.

21 DR. BARRETT: Dr. Zink.

22 DR. ZINK: Mr. Silbermann, you mentioned

1 that you track consumer confidence in produce, produce
2 safety. Can you comment a little bit about how that's
3 holding up and maybe even forecast what sort of time
4 frame we've got to work in here to maintain consumer
5 confidence? I think that's probably what I'm most
6 interested in.

7 MR. SILBERMANN: Well, certainly since
8 September 14 we have been tracking consumer confidence
9 much more closely than we ever have before. Let me
10 say that it is directly impacted by outbreaks.

11 When we had the outbreaks, for example, with
12 Taco Bell and Taco John's you saw an immediate dip.
13 It has slightly risen since the middle of September.
14 It is not nearly as high as I would personally like to
15 see it. I will share the very latest research with
16 you later on. It is a couple of weeks' old I think.

17 As to forecasting, I think the best thing we
18 can do as an industry is obviously to adopt the kind
19 of practices that have been urged on our industry by
20 commodity-specific guidance. The best impact in the
21 marketplace is prevention.

22 As to how long consumers are going to give

1 us, I think they are already judging some of the
2 things that have happened and are responding favorably
3 to those. The steps in California, for example, on
4 the marketing agreement I think have had a very
5 positive impact on the way consumers view us.

6 We have had some evidence of cooperative
7 work like the Center for Produce Safety, who impacts
8 on consumers' perception of how government and
9 industry are working together. I think that is
10 absolutely critical.

11 I will tell you that probably the single
12 biggest thing that stands out from our research in my
13 mind is the credibility that consumers place on
14 various different spokespeople. The number one most
15 credible source of information on the safety of fresh
16 produce comes from farmers.

17 Eighty-six percent of the public put the
18 farmer at the top of the list in terms of speaking to
19 the steps that are taken to ensure that the produce
20 that they grow and harvest and feed to their own
21 families and put into the marketplace is safe to eat,
22 significantly higher than if FDA says it, if USDA says

1 it, even higher than their family physician. An
2 interesting fact.

3 DR. BARRETT: Mr. Guzewich.

4 MR. GUZEWICH: Yes. I have a question for
5 Caroline Smith-DeWaal. She made an observation about
6 the fact that produce needs to be labeled to
7 facilitate traceback. There are some practical
8 limitations to that.

9 In the outbreak like we had in the fall with
10 the spinach, that came in a package, and that makes
11 traceback a whole lot easier. But if I go to the
12 tomatoes that we've had here on the East Coast, by and
13 large, those move through the marketplace unlabeled
14 and to the point of use unlabeled. In fact, they are
15 in boxes only, in large quantities in boxes, and
16 sometimes they are resorted during the distribution
17 system and put in other boxes.

18 I just want know if you have any ideas, how
19 do we work on that? Packaging and labeling alone
20 isn't going to get us there I guess is what I wanted
21 to comment on.

22 MS. SMITH-DeWAAL: Yes, Jack, it's a really

1 good question because these commodities do often move
2 in very different ways, but I have been really
3 interested to see the extent to which labeling has
4 been applied when the industry felt like there was
5 some benefit.

6 For example, if I'm purchasing apples today,
7 I will get an individual sticker saying it's a gala
8 apple from New Zealand, which clearly has been applied
9 much earlier in the chain and has followed, stayed on
10 the apple, all the way through.

11 I think that the traceability issues are
12 protective not only of consumers in an outbreak
13 situation, but also of the industry. We have had
14 similar questions about how to trace back ground beef
15 and other commodities, which similarly are mixed. I
16 think it is a challenging problem, but it's also one
17 that is critical that we address in order to ensure
18 that we don't have another September outbreak.

19 DR. BARRETT: Mr. Silbermann, you had a
20 comment?

21 MR. SILBERMANN: Yes. Jack, I think we have
22 to differentiate between on-product labeling, which is

1 what you asked about, such as stickers on an apple,
2 and case labeling, which is really the critical
3 component that I think sometimes we all miss.

4 The best practices guidelines in the pilot
5 study that we did with CPMA up in Canada clearly shows
6 that there is a way to really narrow down the focus,
7 if we use the technology and the standards that GS1
8 International has put in place, that's the old Uniform
9 Code Council. Those are spelled out in the white
10 paper that we have available.

11 That's what we really need to sit down and
12 take a look at, because there is definitely a way.
13 Even in comingling product from different producers,
14 there is a way to narrow that more effectively, if we
15 use these standards in the existing technology.

16 MS. SMITH-DeWAAL: One other point on that.
17 If my recollection is correct, the Bioterrorism Act
18 does require traceability, so this is already built
19 into the law. It's a matter of how to implement it
20 effectively.

21 DR. BARRETT: Mr. Baca.

22 MR. BACA: This is for Mr. Stenzel or

1 Mr. Silbermann. You expressed concern about the
2 broad, very sweeping warning that FDA provided last
3 September on the spinach outbreak. I was wondering if
4 you had some ideas about how that could have been
5 handled differently.

6 MR. STENZEL: Well, I'll start, Mr. Baca. I
7 think at the very initial stage no one questioned
8 FDA's leadership from a public health standpoint. The
9 ultimate number one priority has to be protection of
10 public health, but very, very quickly thereafter I
11 there is better data and better ability to narrow this
12 down to specifically where the source of dangerous
13 food was in the marketplace.

14 My colleague, Mr. Silbermann, mentioned the
15 way we communicate with the public. The science of
16 risk communication is something that all of us need to
17 spend a lot more time on. I hope that is one of the
18 lessons learned from that outbreak.

19 Simply as case reports were accumulating
20 through late September and October, we had nightly
21 media reports of increasing illnesses. The public
22 across America thought people were still getting sick,

1 but those were simply statistical accumulation of
2 illnesses that occurred prior to September 16.

3 The way were communicating with the public
4 throughout that period, not necessarily the initial
5 statement, that is a decision that FDA will always
6 have to make with public health as the first priority.
7 After that point, how could we more quickly narrow it
8 down to what's the real threat to the consumer in the
9 marketplace today?

10 DR. SILBERMANN: I really can't add much to
11 that. I think that Tom did a great job in answering
12 it.

13 DR. BARRETT: Ms. Lewis.

14 MS. LEWIS: My question is directed to
15 Mr. Silbermann and Mr. Stenzel as well. We have heard
16 a lot today about a request for regulation from the
17 Federal Government. In the absence of that, we are
18 not there, what measures or mechanisms, how have you
19 changed practices to implement the GAPs and the GMPs?
20 Are there any differences that you're dealing with?

21 MR. STENZEL: Well, let me try to respond to
22 that. Clearly, what you've seen with the leafy greens

1 agreement in California is a massive move forward in
2 terms of quantifiable, verifiable specific practices
3 to illustrate that commodity-specific guidance.

4 That practice is going to take place not
5 only in California but across the country. I think
6 the real issue for us as an industry, we are going to
7 take those steps. We are going to do everything we
8 possibly can to make sure that all of our growers and
9 packers and processors are complying with the best
10 practices.

11 What we are crying out for is some
12 endorsement of that from the FDA. As opposed to
13 asking the industry to write our own standards, write
14 our commodity-specific guidance and then have it sit
15 on the website, we really need to have the FDA advise
16 us and advise the public that we are taking the steps
17 that you believe are necessary.

18 MR. SILBERMANN: I would add to that,
19 relative to my comment about the creation of the
20 Center for Produce Safety at U.C. Davis, we have
21 already had discussions with FDA, with DHS, other
22 states folks, and Dr. Roberts mentioned this, too, the

1 need to have the regulatory agencies help us to define
2 the research priorities I think is absolutely
3 critical.

4 Dr. Buchanan certainly has committed to be
5 involved in that. I would love to have Dr. Roberts
6 involved in that and some of her colleagues at other
7 places around the country, because we really have to
8 make the most of the resources we have. I think FDA
9 can play a major role in that area, too.

10 DR. BARRETT: Okay, another round.

11 Dr. Solomon.

12 DR. SOLOMON: Dr. Roberts, thank you for
13 your presentation. During the discussions of the
14 various forums you have been part of, you talk about
15 the science and the ecology and the genetics. How
16 about on the analytical methodology issues, the need
17 for more refined methodologies, validation of
18 different matrices, is that also on the scope of
19 priorities?

20 DR. ROBERTS: Absolutely. I'm sorry I was
21 rushing so on that. That was one of the key needs of
22 science. We have a tremendous body of science out

1 there on new, rapid methods. We don't have as much of
2 a rapid address on collaborative studies so they can
3 be accepted in a regulatory framework.

4 There is just a real critical need from some
5 Agency, hopefully, review of the methods that are
6 there, and, hopefully, trying to garner in more of an
7 active role by AOAC or whatever other organization
8 might be out there that could provide some rapid,
9 collaborative confirmation that these are accepted,
10 that we could use them.

11 Because as I said, if you're in the middle
12 of an investigation -- I think the FDA experts here,
13 they need a rapid response. They need the rapid
14 answer. If you can't confirm for six to ten days,
15 that's just inadequate.

16 DR. BARRETT: Okay. Mr. Guzewich.

17 MR. GUZEWICH: Mr. Silbermann, a question.
18 I'm going to ask you to be precise about your precise
19 comment (chuckling).

20 (General laughter.)

21 MR. GUZEWICH: You in your presentation
22 earlier referred to the need for the FDA to use more

1 precise language when talking about outbreaks of
2 foodborne disease associated with produce. Could you
3 be more precise in what you have in mind there?

4 (General laughter.)

5 MR. SILBERMANN: I'll be as precise as I can
6 be in public, Jack. I think certainly at the time of
7 an outbreak, and Tom alluded to this earlier, it is
8 critical to define, if you're looking at a single
9 commodity, exactly what that commodity is to the
10 extent you can.

11 If it's a bagged product, say that it's a
12 "bagged product." If it's not just a bagged product,
13 and it's the overall product, bagged or bulk, say
14 that. Try and be as specific as possible. Be as
15 specific as possible, as he mentioned, about what
16 additional cases mean when you're reporting that. I
17 understand that is not necessarily FDA, sometimes it's
18 CDC.

19 That kind of risk communication component is
20 absolutely critical because my family doesn't
21 understand it when they hear that on the news. Trust
22 me. That's another piece of it.

1 I think the other thing that I would ask you
2 to do is, to the extent that you can either prior to
3 making public announcements on situations such as we
4 faced last September, involve the industry
5 associations as much as you can to give you the
6 maximum understanding of the distribution
7 characteristics of some of these products.

8 You folks aren't necessarily produce
9 distribution experts. You have become much more
10 expert over the last 10 years. I'll grant you that.
11 To the extent you can, work with us.

12 Let me give you an example. I know this
13 wasn't FDA, but it was another agency. In the
14 Taco Bell situation, there was a lot of confusion
15 about what color onion was actually involved. The
16 particular regional authority in that case, I can't
17 remember if they said it was white onions or yellow,
18 but actually it was the opposite.

19 That was the kind of lack of specificity
20 because an inspector went in and didn't realize that
21 the inside of a yellow onion is actually white once
22 you peel it all the way down to the center, so he had

1 the wrong color in the report.

2 That caused all kinds of confusion in the
3 industry as to what color of onion was this actually
4 that was being implicated. Those are the kinds of
5 things I think talking to the industry at the time
6 that agencies all working in a situation like this
7 would help tremendously.

8 DR. BARRETT: Mr. Baca, one quick question.

9 MR. BACA: This is for Ms. DeWaal. When you
10 mentioned applying HAACP to produce and you mentioned
11 having written plans, did you imply also then that we
12 would require significant or adequate recordkeeping in
13 terms of, for example, if they test the water
14 periodically that they would be able to demonstrate
15 through the investigator that yes, the water had been
16 tested?

17 MS. DeWAAL: Yes. The very important
18 element of HAACP is both planning, putting your food
19 safety plan in place and then also keeping records
20 about what you're doing.

21 The difference here, and I don't really call
22 what we are asking for here HACCP, because I don't see

1 that there are critical control points, per se. I
2 think there are a lot of control points along the
3 chain, but there aren't critical control points.

4 I'm comparing it to seafood HACCP, but I
5 don't think you need a HACCP for fresh produce
6 necessarily, but I think you need to follow the model.
7 Recordkeeping, especially when they are doing testing
8 or ensuring that the water is working, the kinds of
9 records have to be maintained just every day on the
10 farm, those should also be part of the food safety
11 plan.

12 Then, in the audit they are not only looking
13 at the plan itself to see if it's adequate, given the
14 environmental conditions, but they are also checking
15 the records to see that they are maintained and that
16 they say the things to ensure the safety.

17 DR. BARRETT: Okay. The last question.
18 Ms. Lewis.

19 MS. LEWIS: My question is also for
20 Ms. DeWaal. You mentioned about the auditing, and
21 having perhaps state regulators do an audit or produce
22 buyers do an audit.

1 I would like to know your feelings.
2 Sometimes there is a case where a farmer may have
3 audits by several different companies based on what
4 the buyer chooses to have. How do you feel about
5 farmer audits versus those that you mentioned?

6 MS. DeWAAL: The key for keeping the audits
7 trustworthy is that the farmers are not themselves are
8 paying for the audit, but it's being either done by a
9 state or a federal agency or it is being done by
10 somebody who is actually going to purchase the
11 product.

12 I think actually we are stepping out a
13 little on this. This is not a position we have taken
14 with respect to any other food commodity, but I feel
15 in this instance that the buyers have the same
16 interests.

17 The key to the audits that are done by
18 third-party buyers is the fact that they should be
19 done according to these kind of uniform standards that
20 FDA would set.

21 Now, the buyer may in fact have a whole
22 bunch of other quality criteria and other things that

1 they want to audit for as well, but those should be
2 kept separate from this audit that would then be used
3 by the states and the Federal Government in their
4 review.

5 DR. BARRETT: Okay. Well, I would like to
6 thank both of our panels for the presentations they
7 have made. We will adjourn for lunch now and be back
8 here at 1:45.

9 Again, if you look for individuals with blue
10 tags, they can direct to where you want. There is one
11 place to eat right here in the Wiley building. If you
12 choose to go elsewhere, there are places nearby in
13 College Park.

14 Thank you.

15 (At the hour of 12:30 p.m. the luncheon
16 recess was taken, the proceedings to be resumed at
17 1:45 p.m.)

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1 solicit comments from stakeholders, and so after I get
2 done reviewing the questions and issues, then we will
3 hear from the public commenters.

4 For the most part, the invited speakers
5 focused their remarks on issues addressed in "The
6 Federal Register Notice." The remainder of the
7 program, as I said, will be devoted to the people who
8 signed up to give public comments, and we are hoping
9 that they also focus on the issues and questions that
10 are in "The Federal Register Notice." We have a lot
11 of commenters this afternoon, so I'm going to do this
12 as fast as possible.

13 There are three major issues that were
14 identified in the Notice. The first issue was talking
15 about risk factors or factors that contribute to the
16 microbiological contamination of fresh produce.

17 The second issue had to do with FDA
18 measures. You heard about some of them this morning.
19 An example is the 1998 "Good Agricultural Practices
20 Guide," the 2004 "Produce Safety Action Plan," and the
21 sprout guidances in the new "Fresh-Cut Guide."

22 Also, you heard this morning that FDA

1 provided technical assistance to the industry in
2 developing the commodity-specific guidances.

3 Okay. The third issue is traceback, and
4 that is the process of tracking foods back to their
5 source.

6 The fourth issue has to do with records.
7 This is written food safety records or SSOPs/SOPs.
8 It's not the records that have to do with traceback,
9 because the questions about those are under traceback
10 issue.

11 The last issue is that of verification. It
12 is the verification that the "Good Agricultural
13 Practices" have been implemented successfully.

14 As I mentioned before, "risk factors" are
15 factors that contribute to the risk of microbial
16 contamination of fresh produce. We have asked
17 stakeholders to share any information, actually you're
18 the stakeholders, that you have to enable us to
19 identify and understand factors that contribute to the
20 microbial contamination of fresh produce.

21 We are talking about risk factors in the
22 entire supply chain. This morning most of the risk

1 factors that were discussed were those that we see on
2 the farm, but this particular issue we really want to
3 look at the entire supply chain. We want information
4 on risk factors in post-harvest processes, in
5 processing of fresh-cut produce, and the transport and
6 distribution and retail.

7 There are three areas, and they were
8 discussed quite a bit this morning, that appear in
9 multiple steps in the supply chain. Water is a
10 carrier of human pathogens. It is used for irrigation
11 with chemicals and topical sprays. It is also used in
12 other steps in the supply chain to cool or transport,
13 to wash, and in processing of fresh-cut fruits and
14 vegetables.

15 Worker health and hygiene is another area
16 that may cause problems. Workers can transmit
17 disease, foodborne illness. Food handlers often need
18 training. I think Michelle mentioned that this
19 morning. They often need training in food safety
20 practices.

21 Then, the third is environmental sources of
22 contamination. That is a really big area. I think

1 Thomas talked a lot about that this morning: animals,
2 manure, flooding, those kinds of things in the field.
3 Also, the environment might be the environment in a
4 processing facility and how good the sanitation
5 practices are.

6 There are four questions under the first
7 issue, "risk factor." The first one basically is,
8 what are today's risks or practices that could lead to
9 microbial contamination? I'll go through these
10 quickly.

11 The second question has to do with, to
12 paraphrase, what can we do about these risky
13 practices? The third question is, what current
14 practices reduce risk?

15 These are all in your "Federal Register
16 Notice." If you can't read them fast enough, you can
17 read them in there.

18 The fourth question is, what kind of testing
19 of pathogens or indicator organisms is done throughout
20 the supply chain?

21 Okay. The second issue has to do with FDA
22 measures. As I mentioned earlier, FDA has

1 implemented, already implemented certain measures to
2 ensure the safety of fresh produce. The first
3 question under "FDA measures" is, what else does FDA
4 need to do, or do they need to do anything else? I
5 think we heard this morning that they probably need to
6 do a lot. Where in the supply chain should they
7 focus?

8 The next question, how should we consider
9 the wide variation in the produce industry? There's
10 all kinds of variation: variation in size, nature of
11 commodity, practices used, vulnerability to
12 contamination of a particular commodity.

13 Okay. We are at the third. The third issue
14 is traceback. Traceback can be difficult. I'm sure
15 Jack Guzewich and everybody in here would say the same
16 thing.

17 It is particularly difficult with unpackaged
18 produce because of all the packing and repacking that
19 may be done with the produce. There are lots of
20 chances for comingling.

21 It is also difficult with packaged produced,
22 packaged and labeled product, because often the

1 information is insufficient or incorrect. What
2 records do we need to assist in a traceback?

3 Okay. The fourth issue, this refers to
4 records, as I said, other than those used for
5 traceback and includes written food safety plans,
6 SSOPs, HACCP monitoring records, for example. Those
7 are examples.

8 They can be tools for both the industry and
9 the regulators to enhance food safety. They can be
10 used by the growers as well. A grower can do an
11 assessment of the field environment and agricultural
12 inputs which will help contribute to the development
13 of a written food safety plan and SSOPs.

14 The first question for records is, are
15 records useful for risk identification, risk
16 mitigation, or risk management? Does industry use
17 them for that?

18 The last issue is verification. You heard
19 this morning that there is increasing pressure on
20 industry from buyers for industry to provide
21 assurances that their product is safe. They ask for
22 verification from the suppliers themselves or from

1 third party auditors.

2 The question is, how well do these types of
3 verification reflect that suppliers are successfully
4 following the good agricultural practices?

5 How do growers, regulators, and third-party
6 auditors measure and verify that good agricultural
7 practices or other produce safety guidance is being
8 followed? What standards do they use? What effect
9 would any new federal measures concerning verification
10 have on small businesses?

11 Okay. That's it. Now we are ready for
12 public commenters. Here are the ground rules.
13 Speakers are limited to -- well, it's not really
14 approximate.

15 We have so many speakers they will be
16 limited to five minutes each. They will be heard in
17 the order that they appear on the agenda. As the
18 speaker before you is ending his or her comments,
19 please begin to come down to the front of the
20 auditorium so we can move this process along.

21 What we did at the previous public hearing
22 in California is we had the FDA Panel ask questions of

1 the speaker right after they have given their
2 presentation, and I believe we are going to follow
3 that process here. Okay, that seemed to work the
4 best.

5 Oh, okay, just a couple of other things. We
6 are also asking for written comments. This is where
7 you can send your electronic comments. These are all
8 in "The Federal Register Notice." This is where you
9 can send written comments. This is the address. Make
10 sure you include agency name and docket number on the
11 comment submission, and the deadline is June 13.

12 Thanks.

13 (Applause.)

14 PUBLIC COMMENTS

15 MR. LANDA: Our first speaker this afternoon
16 is Perry Bowen from King George, Virginia.

17 (No verbal response.)

18 MR. LANDA: There is some question about
19 whether he made it this afternoon, apparently not.
20 Our first speaker is Thomas Nassif from Western
21 Growers Association.

22 MR. NASSIF: Thank you very much.

1 I am the president and CEO of Western
2 Growers. We represent the fresh produce industry in
3 California and Arizona. We represent about 95 percent
4 of the vegetables and 75 percent of the fruits and
5 nuts that are produced, which is about 50 percent of
6 everything produced in the country.

7 We drafted the California Leafy Green
8 Marketing Agreement, and we are the proponents of the
9 metrics that were used with the "Good Agricultural
10 Practices" which have been accepted by the Marketing
11 Board.

12 As all of you know, the dual mission of FDA
13 is to protect and promote the public health. FDA
14 must, however, place equal emphasis on both aspects of
15 its mission. FDA has a strong record in protecting
16 the public health.

17 While FDA is focused on this component of
18 this mission, more could be done to promote public
19 health. Part of promoting public health is increasing
20 the consumption of fresh produce which FDA has always
21 supported.

22 In March 2004, FDA proposed an action plan

1 to confront the nation's obesity problem and said that
2 increasing the consumption of fresh fruits and
3 vegetables was a critical element of any plan to
4 reduce obesity, the obesity epidemic.

5 In the May/June 2005 publication of "FDA's
6 Consumer Magazine," the article "Healthier Eating"
7 notes the following:

8 "Currently, the typical American diet is low
9 in fruits, vegetables, and whole grains and high in
10 saturated fats, salt, and sugar. As a result, more
11 Americans than ever are overweight, obese and at
12 increased risk for chronic diseases such as heart
13 disease, high blood pressure, diabetes, and certain
14 cancers."

15 As part of the recommendation, the article
16 suggests eating a variety of fruits and vegetables.
17 Specifically, the article urges consumers to get a
18 variety of dark-green vegetables such as broccoli,
19 spinach, and greens.

20 The article even points out that you can buy
21 salad in a bag to make eating vegetables more
22 convenient. However, the net effect of the FDA

1 consumer alert in the spinach alert together with the
2 press releases thereafter has been more to promote the
3 nonconsumption of fresh produce.

4 In addition to spinach, many related
5 commodity groups were also affected by the FDA
6 warning. A loss of confidence in these products works
7 against public health by discouraging consumers from
8 increasing their consumption of lettuce and leafy
9 greens, which public health advocates for urged for
10 years as a means of reducing key diet-related
11 illnesses such as heart disease and diabetes.

12 In this initial alert to the public on
13 September 14, 2006, FDA implicated bagged, fresh
14 spinach as a possible cause of the E. coli outbreak
15 associated with the consumption of produce.

16 Twenty-four hours later, the implicated
17 processor recalled all of the bagged spinach salads.
18 After six months of investigation, it was determined
19 that it was bagged spinach, as they had said on
20 September 14, and that the implicated processor that
21 was identified and recalled their product on the 15th
22 was the same at the end of the end of the six-month

1 investigation.

2 In the meantime, however, the entire spinach
3 industry suffered the consequences. By September 22,
4 FDA had narrowed the scope of the outbreak to three
5 counties in California and advised the public that
6 spinach grown in non-implicated areas could be
7 consumed.

8 To the consumer, they made no distinction
9 because they didn't know where the spinach that they
10 were eating in these bagged salads came from. The net
11 result of the FDA advisory was to damage consumer
12 confidence in all forms of spinach -- fresh, frozen,
13 canned -- grown in all regions of the country.

14 Today, many restaurants around the country
15 still refuse to put fresh spinach on their menus.
16 Believe me, I ask every time I dine out. Even today I
17 noticed in "USA Today" headlines saying, "CDC Reports
18 E. Coli Cases Are on the Rise In the Leafy Greens."

19 Now, there is almost nothing in the article
20 that talks about the leafy greens. It talks about
21 mostly other commodities. And the picture? The
22 picture is a picture of a market saying, "Quarantine

1 all spinach." It's dated 9/15/06. This is today, the
2 April 13 headline in "USA Today."

3 It is FDA, in my opinion, that need to
4 reassure the public that spinach is safe to eat.
5 Recent consumer surveys indicate that the high degree
6 of influence that FDA has and other government
7 agencies have on public behavior, consumers look to
8 FDA as the leading authority on safety of the food
9 supply.

10 Complicating matters was the fact that all
11 the media attention had created an overarching fear
12 that there was a fundamental breakdown in the safe
13 production and handling of leafy greens.

14 A recent report by the Perishables Group
15 reviewed the impact of the spinach recall at the
16 retail level. Packaged spinach saw their sales
17 decrease over 27 percent in the period following the
18 outbreak and over 43 percent lower than the same
19 period the previous year.

20 Packaged salads with spinach were down
21 nearly 38 percent from the prior year and down
22 42 percent from the previous year. The E. coli

1 outbreak also had a devastating impact on the
2 international sales of spinach.

3 Within days of the outbreak, Mexico
4 responded by placing an embargo on all spinach that
5 was exported from the United States. In fact,
6 Mexico's Food and Drug Administration still has an
7 advisory on U.S. spinach.

8 For a number of weeks following the
9 outbreak, Canada also prohibited all spinach imports
10 from the United States. Given the widespread and
11 continuing impact of the outbreak, FDA must
12 acknowledge it has a role in restoring consumer
13 confidence in the safety of spinach and leafy greens,
14 thereby aiding in the revitalization of the industry.

15 Beginning on September 29, 2006, FDA began
16 directing the leafy greens industry to: "Develop a
17 comprehensive plan which is designed to minimize the
18 risk of another outbreak due to E. coli 0157:H7 in
19 spinach grown in Central California."

20 Less than one month later, on October 26,
21 2006, Western Growers' Board of Directors unanimously
22 voted to pursue a three-part approach to creating

1 mandatory food safety guidelines at the state and the
2 federal level.

3 Western Growers along with its industry
4 partners took the first step with the enactment of the
5 California Leafy-Green Handlers Marketing Agreement on
6 April 1, 2007.

7 As part of the marketing agreement,
8 virtually the entire leafy-greens industry has
9 accepted the good agricultural practices that reflect
10 the latest in science and technology. As a matter of
11 fact, 98 percent of the entire industry is a signatory
12 to that. Once they sign, it is mandatory that they
13 comply for the term of the contract.

14 Western Growers is now in the process of
15 developing the next two steps, which include a
16 California marketing order, which would be mandatory,
17 and a federal approach to fresh produce safety
18 regulations that would be mandatory.

19 Clearly, the industry has responded to the
20 call for enhanced food safety measures. Spinach and
21 leafy greens are now safer than they ever have been.
22 Undermining this effort, however, of the leafy green

1 industry, FDA personnel have gone on record recently
2 saying that they do not believe that the food supply
3 is any safer today than it was in September.

4 Furthermore, they have said we are looking "at a
5 distinct probability of an outbreak linked to leafy
6 greens in 2007."

7 While we agree that there is no guarantee
8 against another outbreak, even if the California
9 metrics are adhered to by the entire industry
10 throughout the country, our actions have significantly
11 reduced that possibility.

12 FDA must extend the honest effort to reduce
13 the risk of the production and harvest operations by
14 calling on other parts of the supply chain, including
15 transportation companies, food service companies, and
16 retailers to develop their own robust best practices
17 to ensure the safety and integrity of the product they
18 receive, handle, and sell.

19 Also, FDA should strongly discourage buyers
20 from going around producers who are employing these
21 good agricultural practices in favor of a lower-cost
22 product.

1 Western Growers will be opening an office in
2 Washington, D.C., at the end of this month in order to
3 work further with FDA and other agencies on food
4 safety, immigration, the farm bill, and other areas.

5 Thank you very much for allowing me to speak
6 to this group this morning (sic).

7 (Applause.)

8 MR. LANDA: Questions?

9 DR. SOLOMON: Thank you for that
10 presentation. Help me understand. With the outbreak
11 my understanding is that there were many different
12 bags of product that were out there produced at the
13 same facility, and there were also larger bags that
14 potentially could have been put onto grocery shelves
15 and other places and products that was repacked. How
16 could the consumer be able to identify the product
17 from the specific facility?

18 MR. NASSIF: Well, frankly, I don't think
19 there were any bagged salads that were still out there
20 that were contaminated. As you know, the illnesses
21 occurred in August, and by that time most everything
22 had been purchased.

1 The fact is that the processor who processed
2 that bagged salad and all of the people who use their
3 own brands that were processed by them, all of them
4 recalled their spinach.

5 MR. GUZEWICH: One question. Thank you,
6 Mr. Nassif, for your presentation. You made several
7 times the comment that the FDA should promote the
8 safety of spinach. What do you have in mind when you
9 say that?

10 MR. NASSIF: Well, for example, instead of
11 saying that spinach is no safer today than it was in
12 September, what I would like to have heard from FDA is
13 that what the industry has done is to provide metrics
14 which are far in excess of anything we have seen
15 before from this industry, even the metrics we had
16 suggested when we dealt with them earlier. That has
17 gone a long way toward improving the safety of the
18 food supply so far as fresh spinach is concerned.

19 While these metrics have gone a long way in
20 limiting the contamination possibilities, it is a
21 first step in a number of steps that yet need to be
22 done in cooperation with FDA and with scientists.

1 That would have been a truthful and a very
2 straightforward statement that could have benefitted
3 both the industry and FDA's goal.

4 MR. GUZEWICH: Thank you.

5 MR. BACA: I mean, I agree the steps you're
6 taking are absolutely in the right direction and are
7 very proactive, but I'm concerned with the uniformity
8 of compliance.

9 How can a consumer be sure that every grower
10 in this area is going to get on board with this and
11 whatever they produce and that goes into the market is
12 going to be produced under current state-of-the-art,
13 good agricultural practices?

14 MR. NASSIF: Well, the marketing agreement
15 that the handlers signed, as I said we have 90 percent
16 of the entire industry, and they are bound.

17 MR. BACA: It's that other 10 percent.

18 MR. NASSIF: We know that there is still
19 part of our industry that is not bound. We want
20 everyone to be bound, so our next step is the
21 marketing order, which is going to make it mandatory
22 on everybody.

1 We will probably do a mandatory order for
2 the handlers, because we know the handlers are on
3 board. That means that everybody who grows and
4 anybody who handles in the state of California will
5 have to comply. It will be verified by the state of
6 California and the United States Department of
7 Agriculture, AMS Division.

8 The third step is mandatory federal
9 regulation. The reason we did it in this order was we
10 did those things, we took those steps which would be
11 the quickest in responding to what FDA had asked of
12 us.

13 Thank you.

14 MR. LANDA: Our next speaker is Richard Ross
15 of Path Tracer.

16 (PowerPoint presentation in progress.)

17 MR. ROSS: My name is Richard Ross. It's
18 nice to be with you this afternoon. I'm a 30-year
19 food manufacturer. I've been in charge of
20 19 different food manufacturing facilities. What I
21 would like to talk to you today about is what the
22 growers can do for themselves by doing tracebacks.

1 They are talking about the certification
2 process for fruits and vegetables, particularly with
3 the marketing order, tracebacks are a key.

4 Third-party audits are outstanding, best practices
5 that are adopted are great, but tracebacks are the
6 best thing that you can possibly do to enhance the
7 best practices and the third-party audits.

8 The thing about tracebacks that I don't hear
9 from anybody is the fact that there are two different
10 types. One is the reactive type, and the other is the
11 proactive type.

12 Now, the reactive type is the one that I was
13 always associated with when the FDA would come in and
14 they would say, "We need to see your records." We
15 would open the door and there would be boxes upon
16 boxes of records.

17 When I gave this same speech a couple of
18 weeks ago and I was looking at all the inspectors and
19 all the inspectors were going, "Yes, that's indeed the
20 case."

21 They go for this shoe box and they would
22 look and they say, "Oh, this isn't so good," and then

1 they would go for another shoe box. By the time they
2 were done, they had taken so much time and they were
3 so confused in what they were trying to accomplish
4 that it really lost all effectiveness.

5 Let's talk about proactive tracing.

6 Proactive tracing is where you do an activity log of
7 everything that happens at your facility. If you're
8 talking about a grower specifically, the grower is
9 going to be able to say that "Yes, I planted this
10 seed. I applied this different fertilizer. I did
11 this soil amendment. I had Crew A doing the
12 harvesting. They did indeed have stainless steel
13 knives and dips."

14 In order for them to take care or everything
15 that they need to do, they will be able to demonstrate
16 that then with a proactive system. I think that that
17 is the real key for today for what we are talking
18 about with the leafy green vegetables.

19 Why traceback at all? The fact is, as you
20 can see from this University of California at Davis
21 slide, is that as you increase traceability, you will
22 be able to increase food safety.

1 Now, if you will notice, it is a 1 percent
2 increase associated with where we are today versus
3 where food safety might take you. The reality of it
4 is that is one-third reduction in the differences of
5 the outbreaks. You are going to be able to reduce all
6 of your outbreaks by a third. Traceability is the
7 key, as far as I'm concerned, with food safety in
8 general.

9 You talk about proactive tracing and
10 reacting tracing and how tracing does help. Here is
11 the impact that it had upon the industry over the past
12 six months.

13 One that I like to bring up, besides looking
14 at all the other red numbers that are up there, is the
15 one in the lower, right-hand corner, which is the
16 packaged salad non-spinach group. They lost 8 percent
17 of their sales, and they had nothing to do with the
18 spinach outbreak at all. That's a \$70 million hit.
19 That is just not acceptable in the year 2007.

20 The grower has an advantage by doing this
21 properly. The grower has an advantage because he can
22 say, "Yes, I'm certified. Yes, I'm easy to audit. I

1 can prove that I didn't do it," because of all the
2 things that they have done in advance.

3 The benefit then also goes to the
4 packer/shipper because the packer/shipper is able to
5 say that "Yes, I know that this guy did this, and so
6 my products are going to be safer also." That will be
7 driven all the way up to the consumer. It's just
8 imperative that we talk about something like this.

9 Now, you look at the advantages to everybody
10 along the line. What I would have to tell you is
11 associated with this spinach outbreak, six months for
12 an investigation is just too long. Six weeks without
13 spinach, that's just not tenable in this day and age.

14 If you ever put into effect the Bioterrorism
15 Act, that would give people approximately six days.
16 At six days you would be able to do your analysis and
17 such.

18 Is that really going to get you where you
19 need to go when in 2007 you can actually do a
20 traceback all the way from the fork all the way to the
21 field in less than six minutes?

22 Our product does that. A proactive tracing

1 system will allow you to accomplish that because as
2 everybody keeps track of what they are doing you're
3 going to be able to go all the way back through the
4 system in order to be able to get that traceability
5 and get that kind of effect.

6 It helps everybody including the FDA. If
7 you've got something that is on a Web base, you're
8 going to be able to have information available without
9 having to travel, so the FDA is going to be able to
10 have a more efficient use of their manpower.

11 You are going to have more accurate and
12 complete information because this is kept in advance
13 rather than going to the shoe-box method of trying to
14 find out what you've done and when you did it.

15 The proactive response is also proactive for
16 the FDA and for all the consumers and for everyone
17 else. This is a step forward in accomplishing
18 something that is only necessary for the protection of
19 really the entire food supply.

20 You've got immediate answers. As I said two
21 weeks ago with Dr. Buchanan, I said it is just a
22 matter of just pushing a button. Dr. Buchanan noticed

1 when I was making this speech last time that basically
2 by doing an activity program, you were able to align
3 that with ISO 9000. It is not some guess. It is
4 something I have a lot of particular experience with.

5 She just told me to stop. With that thought
6 in mind, I'll answer any questions.

7 MR. LANDA: Thank you.

8 (Applause.)

9 MR. LANDA: Our next speaker is
10 Michelle Marcotte with the International Irradiation
11 Association.

12 (PowerPoint presentation is in progress.)

13 MS. MARCOTTE: Hello. Thank you for
14 inviting me and thank you for putting up with the
15 technology problems. I am Michelle Marcotte,
16 presenting today on behalf of the International
17 Irradiation Association and it's affiliate, the Food
18 Irradiators Processors Alliance.

19 We are called the "IIA" and we are an
20 association of suppliers of irradiation equipment at
21 over 90 percent of irradiation contract services
22 worldwide.

1 Our membership includes six American
2 companies providing irradiation services in 39
3 irradiation facilities in the U.S. IIA/FIPA and its
4 members have played the leading role in the
5 development of radiation processing for the
6 sterilization of medical and personal care goods as
7 well as for food irradiation for several decades.

8 Irradiation is a physical process that
9 depending on how it is used can kill or control
10 harmful or food spoilage microorganisms on and in
11 foods.

12 It does not involve heat. It is not a
13 chemical treatment. It leaves no residue in the food,
14 and it will not affect the nutrient content of fresh
15 produce.

16 Irradiation should be viewed as part of an
17 integrated food safety system that starts on the farm
18 and carries through to the consumer or food service
19 kitchen. The difference is irradiated produce will
20 land on the kitchen countertop much cleaner, and I
21 mean that in a microbiological sense.

22 Irradiation will kill harmful bacteria such

1 as E. coli and salmonella in and on the cells of
2 fruits and vegetables. Irradiated fruits and
3 vegetables can be eaten raw safely.

4 Research at USDA's Agricultural Research
5 Service in Wyndmoor, Pennsylvania, shows that
6 irradiation could have prevented or significantly
7 reduced the impact of recent infections of E. coli
8 bacteria linked to contaminated spinach and other
9 produce.

10 Dr. Brendan Niemira of USDA ARS wrote:
11 "Irradiation is very effective at killing bacterial
12 pathogens including human pathogens like E. coli
13 0157:H7, salmonella, and listeria monocytogenes on
14 fruits and vegetables including leafy salad products
15 like lettuce, spinach, endive, and other leafy
16 vegetables. Different types of produce have different
17 responses to irradiation, and some are more tolerant
18 of the process than others."

19 Dr. Xuetong Fan also at USDA ARS adds:
20 "Studies conducted at the ARS Eastern
21 Regional Research Center of USDA and other
22 institutions have demonstrated that irradiation

1 decreases or eliminates human pathogens on fresh and
2 minimally processed fruits and vegetables without
3 significant detrimental effects on nutritional and
4 sensory quality.

5 "Our studies on quality of irradiated
6 produce indicate that most of the fresh-cut or
7 minimally processed fruits and vegetables can tolerate
8 a radiation dose of 1 kilogray, a dose that
9 potentially inactivates 99.999 percent of E. coli
10 0157:H7."

11 Dr. Fan asserts: "If human pathogens such as
12 E. coli 0157:H7 get inside of produce, they will
13 unlikely be killed or removed by any chemical
14 sanitizer or wash without damaging the product.
15 However, internalized pathogens can probably be
16 inactivated by irradiation because of its penetrating
17 ability."

18 Dr. Anuradha Prakash at Chapman University
19 wrote: "Irridation is one lethal treatment that fresh
20 produce can tolerate without affecting quality. It's
21 particularly important for fresh-cut products that
22 will not receive further lethal treatment prior to

1 consumption.

2 "Irradiation does not replace good
3 agricultural practices. Given the fact that most
4 fresh produce is processed in large, centralized
5 facilities, irradiation provides additional insurance
6 against foodborne pathogens."

7 Here is the problem. Although FDA has
8 approved the use of irradiation to killed insects and
9 to extend the shelf life of fresh fruits and
10 vegetables, the regulatory approval does not extend to
11 killing harmful microorganisms and does not extend to
12 minimally processed fruits and vegetables.

13 FDA has dragged its "regulatory feet" for
14 several years on several petitions that would have
15 expanded the use of irradiation and improved public
16 health. FDA needs to immediately rectify this lack of
17 regulatory action.

18 Irradiation is already used and accepted in
19 the U.S. Current estimates are that approximately
20 18 million pounds of irradiated ground beef and
21 poultry are marketed in the U.S. annually. It is also
22 estimated that some 8 million pounds of irradiated

1 fruits and vegetables -- mainly mango, papaya, and
2 guava -- are sold annually by U.S. retailers.

3 Spices have been commercially irradiated
4 since 1986, and approximately one-third of commercial
5 spices consumed in the U.S., or about 175 million
6 pounds, are irradiated annually.

7 Here are some companies you may be
8 interested in contacting for further information.
9 Facilities presently irradiating food for human
10 consumption in the U.S., include: Food Technology
11 Services, Inc., located in Mulberry, Florida; Texas
12 A&M University at College Station, Texas; Sadex, Inc.
13 at Sioux City, Iowa; and Hawaii Pride on Hawaii's
14 Big Island.

15 New Jersey-based Gray Star is in the process
16 of finalizing plans to build another gamma irradiation
17 facility near Honolulu, Hawaii, and that facility
18 wills serve Hawaiian growers as well as Asian
19 customers and be operational in mid- to late 2007.

20 Several additional facilities including
21 those operated by SteriGenics, Steris Isomedics, and
22 Food Technology Services irradiates spices,

1 dry ingredients, and garlic. Food Technology Services
2 irradiates fruit for interstate quarantine within the
3 United States. Sadex has an increasing meat and
4 animal feed and supplement business. Hawaii Pride
5 began marketing irradiated produce in the mainland in
6 2001.

7 MDS Nordion, I'm just running through the
8 names of some of these companies here, is the largest
9 irradiation equipment supplier of the food technology
10 services.

11 [Technical difficulties, loss of sound.]

12 MR. ZINK: [In progress.] Virtually, every
13 cell in a leafy vegetable would receive a lethal dose
14 of irradiation. I mean, you made the statement that
15 some tolerate it well and some don't. Well, that's a
16 kind of a vague statement.

17 These products on the market now can have a
18 40- to 45-day shelf life. I wonder, has anyone really
19 done any studies to show that products now in the
20 marketplace could tolerate this kind of dose?

21 Then, second is really a philosophical
22 question, should we be using irradiation to clean up

1 what is essentially an adulterated product if we
2 believe it's possible through good agricultural
3 practices to prevent adulteration?

4 MS. MARCOTTE: Those are good questions,
5 Dr. Zink. In fact, I'd asked them myself. The reason
6 that I just quoted the comments from those three
7 research scientists is that they have done a lot of
8 research, and I didn't have time in five minutes to
9 review it.

10 In fact, the Agricultural Research Service
11 at Pennsylvania, the researchers there, have answered
12 a lot of those questions with very specific and
13 detailed research.

14 You can kill E. coli. It has a low D10 in
15 fruits and vegetables. You can achieve more than a 2
16 log reduction even between the minimum and maximum
17 dose requirements, if we stay with the FDA current
18 maximum of 1 kilogray. It definitely can be done.

19 There are some products that are damaged by
20 this process, but the ones that seem to have, with the
21 exception of tomatoes, caused a lot of the problems,
22 they have done work both on the fresh product and on

1 minimally processed to say that yes, those outbreaks
2 could have prevented.

3 Having a statement of a comment summarizing
4 the research is one thing, reading the research is a
5 different thing, and that's what I encourage you to
6 do.

7 For your next question of whether you should
8 be using irradiation, I mean, do you ask that same
9 kind of question saying, do we really need to be
10 telling people to cook poultry because they should
11 have cleaned up the salmonella before the poultry got
12 to the kitchen?

13 Well, yes, there are some things where a
14 terminal kill step is needed and would prevent the
15 problem. I don't know whether if you've got -- you've
16 had the GAPs/GMP document out. There has been some
17 compliance up till now.

18 Granted, there is probably a lot more
19 compliance now, but you are still not going to
20 terminally prevent, definitely prevent the occurrence
21 of any microorganism in a very complex system like
22 farming. Having a terminal step, the point is that

1 some processors and packers are going to want to use
2 it.

3 We have to get the regulation in place so
4 that people who want to use it can do that. Standing
5 back and sort of saying, "Well, should people really
6 use it or not, that's not the issue?" You know that
7 it is a safe process.

8 Give the regulatory approval, and let people
9 see where it fits and how to use it best. There are
10 some large companies that maybe would like to have the
11 lack of liability of saying, "Hey, when that produce
12 left our facility, we know it was clean inside and
13 out."

14 MR. LANDA: You had a question?

15 MR. BACA: I have one. This is Joe Baca,
16 FDA. Has there been any change in the public's
17 acceptance of irradiated foods in the last few years?

18 MS. MARCOTTE: Yes, I really think that
19 there has been. We see continued marketings of meat
20 and poultry. The Hawaii Pride has been sending
21 irradiated produce from Hawaii into the produce
22 terminal in Chicago in increasing volume since 2001.

1 There have been more and more studies that
2 say that people understand it, and they are interested
3 in it. They see the need for it, particularly in
4 consumers of higher socioeconomic brackets.

5 I think that those are maybe the consumers
6 that are both of the key target markets for bagged
7 salad products and also maybe are the ones that are
8 really aware of the food safety issues.

9 MR. LANDA: Any other questions?

10 (No verbal response.)

11 MR. LANDA: Thank you.

12 (Applause.)

13 MR. LANDA: Our next speaker is
14 Reginald Brown with the Florida Tomato Exchange.

15 MR. BROWN: Thank you. I appreciate the
16 opportunity to be here this afternoon. My name is
17 Reggie Brown. I serve as the executive director of
18 the Florida Tomato Exchange and also the manager of
19 the Florida Tomato Committee, which is the exchange
20 being a growership organization and the committee
21 being a federal marketing order for tomatoes in
22 Florida.

1 The fresh tomato industry in Florida is the
2 largest in the United States and supplies somewhere
3 around 40 to 50 percent of all domestically grown
4 tomatoes to the American consumer.

5 We have actively responded on several fronts
6 upon receiving the CFSAN 2004 letter to growers,
7 packers, and shippers expressing FDA's concerns about
8 fresh lettuce and fresh tomatoes.

9 The Florida Tomato Exchange has worked with
10 other tomato groups throughout North America as a
11 member of the North American Tomato Trade Working
12 Group, or "NATTWG," to address these concerns.

13 Currently, we are working with the Food
14 Safety Division of the Florida Department of
15 Agriculture and consumer services to establish a
16 mandatory state regulation for food safety for
17 tomatoes in Florida.

18 These regulations are being drawn from a
19 number of guidelines including the 1998 FDA "Guide to
20 Minimizing Microbial Food Safety Hazards for Fruits
21 and Vegetables", the 2006 NATTWG document, the
22 commodity-specific food safety guidelines for the

1 fresh tomato supply chain, and others.

2 We have actively engaged with FDA, USDA, and
3 the Florida Department of Agriculture and Consumer
4 Service to explore dialogues and communications in an
5 effort to establish the most effective, science-based
6 regulations to address the risk factors for fresh
7 tomatoes.

8 Addressing this issue in such a manner
9 allows for collaborative efforts to maintain public
10 confidence in the purchase and consumption of fresh
11 tomatoes.

12 The impact of the loss of public confidence
13 is extremely high and will result in injury to all
14 segments of the tomato industry. The main goal must
15 be to prevent foodborne illnesses.

16 In addressing the questions you ask in your
17 "Notice," issue one, every segment of the supply chain
18 must evaluate their specific risk factors and the
19 necessary policies and procedures to manage them.

20 While risks are universal, the mitigating
21 processes and procedures must be established with
22 consideration for specific production, packing, and