UNITED STATES
DEPARTMENT OF AGRICULTURE

IN THE MATTER OF:)
)
PRESIDENT'S COUNCIL ON FOOD SAFETY)
Strategic Planning Task Force)
)
Public Meeting)

Pages: 1 through 263

Place: Washington, D.C.

Date: January 19, 2000

HERITAGE REPORTING CORPORATION
Official Reporters
1220 L Street, NW, Suite 600
Washington, D.C.
(202) 628-4888

IN THE UNITED STATES DEPARTMENT OF AGRICULTURE

IN THE MATTER OF:)
)
PRESIDENT'S COUNCIL ON FOOD SAFETY)
)
Strategic Planning Task Force)
)
Public Meeting)

Federal Hall
Washington Plaza Hotel
10 Thomas Circle, N.W.
Washington, D.C. 20005

Wednesday,
January 19, 2000

PARTICIPANTS:

SUSAN ALPERT
RHONA APPLEBAUM
BARBARA BILLAUER
TOM BILLY
EDWARD BRITT
LAINA BUSH
MILDRED CODY
ROBERT COLETTE
KAREN DEASY
CAROLINE SMITH DeWAAL
NANCY DONLEY
LOU DOOLEY
BERNADETTE DUNHAM
STAN EMERLING
MARY FINELLI
CAROL TUCKER FOREMAN
CLIFF GABRIEL

GENARO GARCIA
MARGARET GAVIN
JERRY GIBSON
JESSIE GREENBLAT
JANE HENNEY
RANDY HIFFMAN
TOM HIGGINS
MARTIN HIRSCH

PARTICIPANTS: (Continued)

JIM HODGES
SCOTT HOLMES
BEN JONES
BRET KAY
KARLEASE KELLY
LYNN KOSTY
BILL KRUEGER
BETH LAUTNER
MICHAEL LAVOLLAY
JUSTIN LeBLANK
DION LERMAN
JOE LEVITT
JIM MANN
DAMIAN MARTINEAU
BERT MITCHELL
KLAS MOLIN
ELSA MURANO
JUDY NELSON
CARL OSAKI
STEVE OSTROFF
DOUG PARK
STUART RICHARDSON
DOUG SAUNDERS
BERNIE SHIRE
DEAN SIENKO
MERYL SOSA
DAN SOWARDS
STEVE STEINHOFF
JENNIFER STEVENS
SUSAN WAYLAND
GREG WEATHERMAN
DEBORAH WHITE
JAMES WHITNEY
CAREN WILCOX
ELIZABETH WISE
CATHERINE WOTEKI
STACEY ZAWEL

P R O C E E D I N G S

(8:45 a.m.)

DR. WOTEKI: Good morning. I'm Cathy Woteki, and I would like to welcome all of you to this meeting. As you know, it is being held under the auspices of the strategic planning task force of the President's Food Safety Council. And that council was established to strengthen and also to focus food safety policy and resources in this country.

As one of its major tasks, the council was directed to develop a comprehensive federal food safety strategic plan. We who have been working as the strategic planning task force have about six months remaining before we have to deliver our final document to the President's council and to the President in July of this year. This has really been a very challenging and multiagency effort, which I think reflects in many ways the complexity of the challenges that we face in ensuring the safety of the American food supply.

The task force felt that the plan has developed to a point where we needed to hear your views, and essentially to step back from the work that we have been doing so far and to hear your views. That is why we are here today. And I think we all are going to benefit from the sharing of those views.

Now despite the confidence we have in the safety of the food supply today, we are still confronted by a significant number of cases of food borne illnesses in this country. I'm sure you are all aware of the recent estimates that the Centers for Disease

Control have provided and which have also been very helpful to the strategic planning task force. However, there are more microorganisms and other hazards continuing to emerge, and some intractable problems continue to cause illnesses.

So one of the tasks of this plan is to ensure that the food safety system continues to evolve to meet those old as well as new challenges. At the same time, nearly a quarter of the population is particularly at risk or susceptible to food borne illnesses. It is also important to develop a comprehensive and forward looking strategic plan to ensure the safety of the nation's food supply into the 21st century. And as a result, the task force that Dr. Henney and I are cochairing feels that this is an extremely important meeting in the development of the strategic plan and in the directions that that plan is taking.

Your contributions to the dialogue today, and we hope over the weeks to come, are critical to enriching a plan that will provide an effective system capable of responding to and preventing food borne illnesses and hazards.

Now many of you here today also attended the last meeting of this task force, public meeting of this task force, in July of 1999. And I hope that you will see that there is very -- there are very substantial differences in the plan that is under discussion today from that one that was made public in July. It now contains three goals that are framed around risk assessment in science, risk management, and risk communication. Each of these goals is accompanied by a narrative, objectives, and action items that are intended to achieve the goal.

These changes are a result of the many very substantive and thoughtful

comments that were received at the July meeting, and also many of the written comments that have been submitted after the meeting. We expect that this meeting today will help us to refine the strategic plan even more.

Now I would also like to point out that the task force is doing a more comprehensive examination of legal authorities as part of its strategic planning effort. That examination looks at a variety of proposals and may result in legislative initiatives that go beyond the current proposals. The administration has already asked for more legal authorities to strengthen our food safety statutes, particularly in the area of recalls and civil penalties. We would welcome comments during the meeting today as far as views of what are barriers in legislation to attainment of the goals and objectives of the strategic plan, as well as potential statutory changes that you view would be meaningful and helpful additions to the current authorizing statutes.

Now before we talk specifically about the format for today's meeting, let me introduce two people who have played extremely important roles in the work of this task force. The first is my cochair, Dr. Jane Henney, commissioner of the Food and Drug Administration at the Department of Health and Human Services. And she will be followed by Ms. Susan Wayland, who is deputy assistant administrator for prevention, pesticides, and toxic substances at the Environmental Protection Agency. They would both like to make some opening remarks. So we will start with Dr. Henney.

DR. HENNEY: Well, let me add my words of welcome to all of you here today in our latest series of public meetings. We have enjoyed very, I would say, both

broad and deep input from the community in terms of our task force's work to date, and we look forward to what this meeting holds for us as well.

I think I would like to underscore a few points already made by Dr. Woteki. I think we want to make sure that we emphasize how much your comments meant to us last summer because it was based on many of these comments and concerns that we really stepped back, evaluated the approach that we were taking at that time, and really redefined many of the specific goals of the plan that you saw in the summer.

In addition, we have added more detailed objectives and action items to flesh out some of the steps that might be taken to achieve this plan's overarching goal, which is really protecting the public health by reducing food borne hazards. It is going to be not just important to us, but important to the work that we all do in protecting the nation's food supply to make sure that we here enact on the public input on the direction and focus of this plan as we further define the specific elements.

Again, you know, as we are working under a vision statement that was developed some time ago, and I have already stated our overarching goal with respect to public health, but we are working now within the constraints of three goal areas, in science and risk assessment, in risk management, and furthering our efforts in terms of risk communication. We believe it is integral to not keep these -- although we want to discuss each of them separately, we also need to see the linkage and integration between and among all of these separate goals because it is only if we are able to do this that we will really achieve our vision for public health and food safety.

We want to make sure that we get responses to some very specific questions. In particular, are there issues or specific tasks that are not identified that you think should be part of the strategic plan. Another question that we have is we have identified priorities and chosen action items that we believe will result in a real difference to the public health, but we need to hear from you as to whether you believe the same in this regard. And I think we also need input from you in terms of how we move forward together to increase the food safety and protect the public health in the United States.

There are a number of other questions that I think have been posed to the panel that were also raised as we issued this public document that Dr. Woteki may be going over once again. We want to listen to all of your responses, your thoughts and concerns about the plan to date. Each of our agencies, the FDA, the USDA, and the EPA, have opened a public docket that will allow people beyond this room to have their own input into this process. And the docket will remain open until February 14th of this year. So as you or others that you know have thoughts and concerns that you want to raise post this meeting, please feel free to do so.

Another reminder of something that has been said, we intend to meet that deadline that we have been given in terms of issuing a final report and strategic plan and providing that to the President's Council on Food Safety this coming July. We believe that plan will be based not only on what we have done to date but what we hear from you today and what we hear from you in the coming weeks and months ahead.

I want to thank you for your participation. I feel myself one of the most

unfortunate in this room because I am not going to be able to be here to hear all of your deliberations, as I have been called to a meeting across town in my own department, which I have been told I must attend. So I will. But I have set aside time so that I can not only review what is said here today, but to also spend some time on that public document as we receive it in February.

I do hope I will be able to rejoin you later this afternoon. I wish you well, and I look forward to hearing all of the discussion, debate, concerns that you have during the course of the day. Susan?

MS. WAYLAND: Thank you very much, Jane. Good morning, everybody? Is my mike on? I can't -- it is hard for me to tell. But I want to first echo Dr. Woteki and Dr. Henney's welcome to all of you. It is truly wonderful to see so many people here, to see old friends and new faces. This is a very important and serious issue, and I think it is terrific to have the number of folks and the amount of support that we have in this room today to help us with our mission.

On behalf of EPA, I want to thank all of you for coming here today to help us fulfill the charge that we have from the President and the council to develop a comprehensive strategic plan that will ensure the safety of the U.S. food supply for years to come.

Food safety is actually a very high priority at EPA. For those of you who have not yet memorized the EPA strategic plan, we do have ten strategic goals that we have articulated as part of our Government Performance and Results Act. And in addition

to those areas that you probably think of more with the EPA, like clean air, clean water, healthy ecosystems, safe food is one of the strategic goals of the Environmental Protection Agency.

We are concerned not only about the pathogens in the food supply, but also about the chemicals that may inadvertently contaminate the food supply, and about pesticide and pesticide residues, which, of course, are intentionally added to help us grow the food in this country.

There has certainly been an increased emphasis on food safety at EPA since the passage of the 1996 Food Quality Protection Act, or FQPA. Developing a strategic plan for FQPA and having that plan fit into the work of the council and developing a comprehensive plan for the nation in protecting the food supply is a very big job, but it is a job that I know that we can do. And with your help, I think we will make great progress on that journey today.

The strategy is really a way to focus, all of us, those of us in the public sector, those of you in the private sector, on the important goals that all of us face in reducing food borne illness and hazards. Certainly, for EPA, our experience in working with these other agencies, just as far as we have gotten, has been tremendously valuable. And I think that working with the public has been tremendously valuable already in developing a comprehensive plan.

We know that our work in the pesticides arena, in our implementation of FQPA, has taught us in a very real way how tremendously important and valuable public

input is. And working with our stakeholders, working with the states, working with our other partners and with public interest groups and environmental groups, I think it enriches this debate, and will result in a strategy that really does address the challenges that the President gave us.

I am very much looking forward to hearing all of your comments today. I would echo both Dr. Woteki and Dr. Henney by saying that we really are here to listen. We truly value all of the input that you are going to be giving us today. And I really look forward to a very rich conversation throughout the day. Thank you. I'll turn it back to Dr. Woteki.

DR. WOTEKI: Thank you, Susan. Let's now talk about what we are going to do today. I would like to first of all highlight some of the themes that we have identified in the development of this plan. These are more fully discussed in the draft that was posted on the web. But I think they are worth noting as we begin to have a more in-depth discussion of the plan and its goals. And the themes are six in number.

The first is the food safety system must be based on sound science and risk assessment, as recommended by the National Academy of Sciences. The second theme is priorities must be selected based on where the scientific data show the greatest food safety risks. The third theme is objectives and actions must be measured in terms of their impact on public health. The fourth is prevention. Prevention of food safety problems must be emphasized. The fifth is fair and even-handed oversight and enforcement of laws and regulations by the responsible federal, state, tribal, and local agencies is critical. And

lastly, we must better coordinate our efforts and the use of our resources.

These themes are important to emphasize in the plan, and are really the threads that kind of tie together the action items under each of those three goals. So as we go through the goals and objectives and action items and further discuss them today, I think it is worthwhile to keep these themes in mind and think of them as measures against which we want to evaluate the action items.

Now for the format of today's meeting, for those of you who have participated in the past public meetings that we have held, and more recently, the one in July of '99, I am sure you can see that there is a change already in the format of the room, just the way this room is set up for today's meeting. Our objectives, though, are the same, to have an active dialogue among all of the communities interested in improving food safety in this nation.

That dialogue is important to create a plan that improves food safety in the United States and serves as a foundation for bringing about what many of us have talked about as being a seamless food safety system from farm to table. Now just in setting up the room today, what we tried to do is to strike a balance between promoting discussion and seating anticipated were going to be 150 participants in today's meeting.

You'll notice that the focal point of the room is this large almost square table. And there are also smaller tables all around the edge of the room. As we move through the agenda, we expect that some participants are going to want to participate more actively in discussion of specific goals or specific action items, and they are perhaps

less interested in discussing another goal or set of action items.

So at the beginning of each segment of the agenda, we are going to ask those who have a lot to say to move up to this table, and those of you who are anticipating that you'll have less to say about that goal, to take a chair either along the row of chairs on either side of the room or at one of the round tables.

Everybody, though, will have an opportunity to say something about the goals and objectives, no matter where you are seated, whether it is at this table or away from the table because you can see that there are microphones that are set up all around the room. So if you have something you want to say, just come up to one of those microphones, and we will recognize you.

I would also like to indicate to you all that there are many members of the task force that are here. And as I look around the room, I think most of the members of the task force are here. And there are also many people who have participated in some of the working groups that have developed initial outlines and text and ideas that the task force has developed into the draft document that you see. And I might just ask at this point that all the people who are members of the task force who are here today, if you could raise your hand so people around the room can see who you are.

(Show of hands)

DR. WOTEKI: You might in breakout session or breaks want to approach one or more of these people with an additional idea that you might want them in particular to know.

I might also ask people who are members of one or more of the working groups who are here if you might also raise your hands.

(Show of hands)

DR. WOTEKI: So there are a fairly significant number of people also here who have participated in the working groups.

Clearly, it is a benefit to all of us who have worked on the development of this text to hear all of the ideas. I am really glad as many members of the working groups and the task forces could be here today.

Now let's just briefly look at the agenda. After this opening portion of the meeting, we have asked three people to at least get us started in the discussion about the plan. And I'm going to come back in a moment to introduce those three members of that panel. After the opening panel discussion, we are going to take a short break. And then we are going to move into a discussion of the overall framework.

Now if you look at your agenda that you received when you checked in at registration, we'll see that there are three questions that we are going to use to focus and direct the discussion about the structure of the plan. At 11:15, we'll go from the overall plan to addressing the individual goals with their respective objectives and action items. And we'll just proceed from the first to the second to the third.

So the first is the goal about science and risk assessment. And again, if you look at your agenda, you'll see that there are four questions on the agenda that we would like to use to focus the discussions. You'll also see that one of those questions has to do

with organization, the organization of the federal agencies. And we would like as well for you to comment at each point for each of the goals on whether there are certain organizational structures that were described under the list of -- or the paper on options that was included again on the web document as to which ones would help to forward the achievement of the goals and objectives.

And after lunch, we will reconvene at 1:45. We'll have a discussion of the risk management goal, again focusing on those four questions. And lastly, we'll end the afternoon with a discussion of the risk communication goal.

That last session this afternoon will be chaired by Caren Wilcox, who is deputy undersecretary for food safety at the Department of Agriculture, and is seated to my right here at the head of this table, and also by Joe Levitt, if Dr. Henney is not able to make it back this afternoon.

Now I want to make clear that the format is intended to be interactive. We did start this morning with some opening comments. But it is probably going to be the last that you are going to hear from us, other than to ask some provocative questions as we go along. Prepared remarks that any of you might have can be submitted in writing to the dockets that are open at all three of the agencies that are represented here, the Food and Drug Administration, the Environmental Protection Agency, and the Food Safety and Inspection Service, and written comments and information about how to submit written comments was detailed in the Federal Register statement and is also included in a handout that you should have received as well when you picked up your registration materials.

So everyone is encouraged to participate regardless of where you are sitting. We are going to have this meeting transcribed, so we will have a formal record. And when you begin your discussion, it would be very helpful to all of us here if you first start by giving your name and the organization that you are here representing.

Now the first item on the agenda then is to move to the panel discussion. We have asked three people to get us started this morning by making some remarks on the strategic plan. They were selected as in some ways representing the major communities that have an interest in food safety. But we also, when we asked them if they would make some comments, told them that in no way would anyone here be expecting that they were representing completely in any way the views of the communities from which they come.

So I would like to introduce all three panelists, and then ask them to get us started in this discussion. First, speaking as an expert in public health is Dr. Dean Sienko. Dr. Sienko works as the medical director of the Ingham County Health Department in Lansing, Michigan, and he has been working there for the last 12 years in that capacity. From the consumer community is Mrs. Nancy Donley, who is president of Safe Tables Our Priority. It goes by the acronym STOP. And thirdly, from the private sector, is Dr. Rhona Applebaum, who is executive vice president for science and regulatory affairs at the National Food Processors Association, a position that she has held since 1994.

So our invitation to be on the panel was not intended to put these people on the spot for their entire communities. We just wanted them to help get this discussion started. And I want to say we really appreciate your willingness to take on that

responsibility. So, Dean, would you like to start us off?

DR. SIENKO: Thank you. As you heard in the introduction, my background is largely in local public health. Some of my comments will reflect that orientation, I'm certain. At one point in my career, my card said medical epidemiologist, and my role was to crunch numbers. Now as a local public health official, I usually try to get my message across by telling stories.

So to help you appreciate my perspective and to put you in my frame of mind, I would like to dissect aspects of the first well studied e. coli 0157:H7 out break that occurred in Traverse City, Michigan in the early 1980s. It began with a nurse, a health practitioner and consumer, who had a child with bloody diarrhea. She talked about this illness with her physician. This local physician noted that there were other cases of bloody diarrhea with a compatible clinical picture. So he took specimens and notified his local health department of this unusual occurrence.

He received the first tier and the rudimentary elements of the public health side of the food safety system, the informed consumer and knowledgeable health care providers who think beyond the clinical illness and relate to public health. If the CDC estimate is that one of three people suffer a food borne illness annually, then where are these people? We see but a sliver of them. We have a tremendous gap to overcome in food safety knowledge among our citizenry and our health care providers.

Finally, when doctors report to the local health department, local, state, and federal disease control investigators worked cooperatively to conduct the

epidemiological analysis of this outbreak. They found that hamburger consumption from a fast food restaurant was associated with illness. This was followed by local environmental health staff who worked with the restaurant to uncover a malfunctioning grill that accounted for some hamburgers being undercooked.

Ultimately, this investigation led to the identification of the e. coli 0157:H7 pathogen and a further understanding of this food borne threat.

Here we see the second tier of public health, the professional system, responding to surveillance supportings, conducting an epidemiological analysis, using the results of that analysis to prevent further cases and enhance our knowledge base.

So does the strategic plan respond to these things? The overarching goal does not mention consumer complaint, surveillance, or outbreak response, all key elements of the above scenario, and the public health role in food safety. The plan could do more to promote not only data collection but data sharing. Many argue that the outbreak of the future involves sporadic and geographically dispersed cases of illness. Effective surveillance and real time data sharing will help us respond to such occurrences.

The plan talks about education, but we need to underscore its importance. From consumers to doctors in emergency rooms to public health nurses in local health departments to laboratorians in state health departments, all need the knowledge and capacity to respond appropriately and work cooperatively on food borne illness. The plan gives me hope. It mentions state of the art science based education. Federal institutions can play an important role by developing such educational tools and working with us to

disseminate them and to train appropriate audiences in our communities, both public and private, professional and lay.

More informed consumers, professionals, and employees in the food industry will lead to a successful plan. The ultimate measure of success is greater prevention and less human illness. And although the plan is referred to as a federal strategic plan, the President's mandate of safe foods for Americans will require a national effort, and this will require an improved infrastructure, better coordination involving both public and private sectors at the state and local levels.

The encouraging part of this initiative and this plan is that we have consensus on where we want to go, safe food for consumers. This plan offers a beginning for the dialogue on how we are going to get there. Thank you.

MS. DONLEY: Good morning, everyone. I am Nancy Donley from STOP, Safe Tables Our Priority. I would like to thank you for being asked to participate today. And it's a pleasure to be here. I am from Chicago, and I have been kind of entertained by what happens to Washington, D.C. when there is a little tiny bit of ice.

(Laughter)

MS. DONLEY: I am just going to say very, very briefly a little bit about STOP and who we are for some of those who may not know. We are a food borne illness victims' organization, and we represent the people -- our membership are people who have been personally impacted by food borne illness or have had loved ones or family members personally impacted by food borne illness. We also represent concerned citizens

everywhere.

My involvement got started with the death of my six year old son from eating e. coli 0157:H7 contaminated meat. And we are very committed to food safety, and we would like to thank the administration and the various food agencies here for their support and commitment to food safety. And we hope it continues and continues to grow stronger and stronger.

I would like to just begin my comments with -- I'm going to be talking some very general types -- making some general observations of this strategic plan. And I would like to start with the vision statement and overarching goal. The vision statement -- and both of these are very laudable. But I have a concern that if the vision statement becomes a publicized statement that the public will stop reading after the first or second lines. And what -- I will just quickly state that the first line says that consumers can be confident that food is safe, and that the second lines says we protect public health through a seamless food safety system that uses farm to table preventive strategies and integrates research, surveillance, inspection enforcement, and education.

It sounds like there is no problem, we don't have to be concerned, food is safe. Then I question where our overarching goal goes on to say that the goal is to protect public health by significantly reducing the prevalence of food borne hazards, thereby reducing acute and chronic illnesses and injuries.

I perceive this as a conflict. On the one hand -- we have got conflicting information here. On the one hand, we are saying food is safe. But on the other hand, we

are saying we are going to reduce food borne illness and death. So there is a problem here that I think needs to be discussed and addressed.

I'd love to be able to say that our food is safe, and I think everyone in this room is, and that we don't have to worry about it. But the way this is structured right now, the public will take it to mean that the food is safe when they get it, and therefore it is a no risk thing for them. So I'm very concerned with that.

The second observation I would like to make is that all these goals, I think, are very laudable, but somewhat unspecific. So I would like to encourage the development of very measurable goals with accountabilities built in as well. I think a key point missing as well that I would like to suggest is that there are no timelines right now in this document. And I think that it is necessary that when you set goals, to have it within a structure, a framework, of time and what specifically you want or you can have. It can be a five year and keep narrowing it down. But it has to be measurable within certain time frames.

I also am concerned -- I think again that these sound terrific on paper, but where is the funding going to come from. I don't see anything mentioned in the plan as it currently stands on funding, funding this issue. So I would hate to see all of this hard work that I know the task force has done and put this together, and the commitment that we all have to this, just be a waste of time and effort because the funding isn't there. So I think we need to have some of those specific things addressed.

And lastly, I just want to comment that it is absolutely crucial that what --

where we take this plan, where we take this document, be founded on a very solid foundation. We have to have -- to build a structure and to have all of these admirable goals, you can't just keep piling on and on. I pay my bills by being a real estate agent. And I know enough about houses and structures that if you don't have a good foundation, a solid foundation, a cohesive foundation, one that is fully cemented and there are no cracks, the structure will not -- you will not support the structure of the building itself.

So we have got to have not such a fragmented system. We have got to somehow solidify it and create a solid foundation. So I hope these remarks are -- I hope these remarks are kind of helpful for starting the discussion today.

DR. APPLEBAUM: Thank you and good morning. NFPA appreciates this opportunity to provide comments. The time allotted to me this morning will not permit me to go into detail on all of the aspects of the plan that NFPA supports, as well as those aspects of the plan we feel require more attention. However, you can rest assured that NFPA will be providing detailed comments on those particular issues. In fact, we will be comparing this draft plan very closely to our own food safety agenda, an agenda we developed to guard our public activities in the area of food safety.

Preliminary comparison of our five objectives with the plan's three principal goals indicates we the industry and the federal agencies that regulate us have the same goal, to ensure to the extent possible the safest food supply. In fact, our food safety philosophy embraces the strengths of this plan, a commitment to scientifically sound preventive systems as the key to ensuring a higher level of food safety assurance. Further,

we both recognize that food safety is a shared responsibility requiring the attention not only of government but of companies throughout the food system, as well as safe food handling practices by consumers and commercial food handlers.

Our commitment to sound science and risk assessment has been articulated in numerous comments, as is our commitment to research, surveillance, and education. With that said, NFPA wants to compliment on the government on the drafting of a plan that is first and foremost bold and designed to enhance, advance, and build upon strengths currently existing in the agencies at all levels of government and others in the public and private sectors.

Despite criticism we know you will face, the decision made to build upon a foundation that has been successful rather than raising and undercutting all of the progress that has been made is the right decision, and we support your action.

I would now like to remaining time to focus on specifics of the plan, beginning with the overarching goal and framework of the plan. I will address the questions laid out for each goal. Those I don't comment upon will be covered in our written comments.

As I mentioned earlier, NFPA is supportive of the strategic plan's overarching goal, which is to protect public health by significantly reducing the prevalence of food borne hazards through science based and coordinated regulation, inspection, enforcement, research, and education programs. We think this is a well focused and comprehensive plan. NFPA also supports the plan's overall framework, which sets goals

for science and risk assessment, risk management, and risk communication.

The remainder of my comments will address the draft goals outlined in the strategic plan, beginning with science and risk assessment. It has long been our position that government resources should be direct toward the areas where there is sound evidence of real risk. This position is clearly reflected in the strategic plan's first goal. In fact, as was mentioned earlier by Dr. Woteki, the draft strategic plan notes that the National Academy of Science's position that, "The food safety system must rest on sound science," is a point that has been repeatedly by NFPA.

We agree with the draft plan's objectives of expanding surveillance and data collection capabilities to better identify emerging and potential high risk food safety threats. We recommend that the council add an action item to expand active surveillance programs such as Foodnet to provide the most accurate data. In particular, we support the establishment of extramural programs to conduct targeted research and develop training programs, especially with regard to using public, private, academic consortia, as this ensures that research and training will be practical and applied.

We also support the strategic plan's objective of enhancing the scientific infrastructure and skills, and improving the coordination of activities at the federal, state, and local levels. NFPA strongly believes that food safety partnerships among federal, state, and local health agencies will only be effective if they are well coordinated. As far as the risk management goal, NFPA has no disagreement with the strategic plan's goal that the United States system for managing food safety is effective from farm to table.

We have no agreement with this goal. We believe that a holistic approach to a well-integrated and coordinated food safety system is vital to enhancing the effectiveness of our nation's food safety system. We strongly support a number of the objectives suggested to support this goal.

In the time remaining, I would like to focus attention on objective one under the risk management goal, specifically the two action items. First, we strongly support the need to harmonize standards and regulations between state and federal governments and among federal programs. If the issue concerns food safety standards and regulations based on sound science, there is no reason for having different national, state, and local standards and regulations. It makes no sense from a food safety standpoint.

As for the second action item under this objective, that is the need to build the infrastructure to support a seamless federal, state, local food safety system, we strongly recommend you elevate this action item to an objective. We also urge attention be given to the need for strong oversight and internal auditing to ensure accountability of the process.

As for objective two under this goal, we support what you are saying, but caution you to be very careful in your wording. The use of the phrase, and I quote, "preventive techniques and controls using risk based approaches," has the potential to be misinterpreted to support the use of a precautionary principle or approach as defined by our colleagues across the ocean. NFPA knows this is not what is meant, but we urge you to use such terms as, "science based risk assessments," more freely in the phrasing of this

objective.

One objective contained in the strategic plan that I would like to address specifically is expansion and enhancement of inspections and performance standards. We are concerned that the strategic plan's focus here is on expanding government's enforcement authority rather than targeting existing authority and resources to ensure that they are most effectively applied.

NFPA feels that certain changes would result in more efficient inspection regulation of the food industry. Much can be accomplished by cooperative efforts among agencies, both at the federal and state levels. Such cooperative efforts should target a risk based food regulatory inspection system which focuses all available resources, regardless of whether it is for meat, poultry, seafood, eggs, dairy, or vegetables onto areas where attention is warranted. Thus we support the plan's objective to prioritize inspections by risks to public health and allocating resources accordingly. We also support the objective for consistent training and consistent enforcement.

On the risk communication goal, while enhanced risk assessment and risk management certainly must be key components of any successful food safety strategic plan, it is the area of risk communication that may pay the greatest dividends in protecting consumers. Therefore, NFPA strongly supports the strategic plan's stated goal that the U.S. food safety system openly and effectively provide information on food safety risks and education on how to control these risks.

NFPA has long urged expanded efforts by FDA, USDA, EPA, and CDC to

educate the public on food safety. Education efforts should be aimed where they will have the most impact, for example, in the schools and in local newspapers, and industry should be a part and must be a partner in this educational activity. Extending education to the general public must involve partnerships among industry, government, and the media, and others in the public and private sectors.

Moreover, food safety experts in the government should actively promote safe food practices and processes. NFPA urges you not to lose the opportunity of using the dietary guidelines for Americans as a vehicle for educating the public on safe food handling practices. While we strongly support public education efforts by government, we are concerned that the plan's stated objective of providing "rapid access" to information about food safety surveillance safety hazards, outbreak actions, and enforcement may be misplaced.

While NFPA supports the use of all tools available to recognize and find sources for food borne outbreaks, it is imperative that rules be established that will maintain security of preliminary information and assure that information is properly reviewed before public release. Although it is tempting to opt to err on the side of safety and inform the public of all of the possible risk factors, our experience is that this is overly conservative and can negatively influence the effective handling and resolution of a food borne illness outbreak.

Subsequent messages regarding food borne outbreaks have diluted effectiveness, especially when the message changes. Thus the public and the regulatory

agencies are better served by targeted and accurate messages about food safety problems. It is our strong belief consumers should be notified of food recalls only when the products in question pose a threat to consumers and consumers need to take action. Releasing information to media and consumers on each and every recall would overload consumers with nonessential information and very critical alerts on which consumer attention should be focused.

A final area I wish to address is consideration of organizational changes to the way that our nation's food safety system is governed. The current regulatory system in the U.S. has provided the framework for what is generally regarded as one of the safest food supplies in the world. While enhancements to the effectiveness and improvements to the coordination of this system should be sought, we must not lose sight of the fact that the current system has been highly effective in protecting consumers.

To become more effective, regulatory agencies must adopt a scientifically sound, risk based approach to developing and implementing regulatory policies, as outlined in the strategic plan. Cooperation within the existing system can produce the desired results.

In conclusion, NFPA supports a strong government program to provide every reasonable assurance of the continued safety of America's food supply. By working cooperatively, consumers, industry, and government can continue to achieve the highest levels of food safety. We thank you for this opportunity, and we will carefully study the plan and provide detailed comments at a later date, including suggestions on how to

evaluate progress and measure success.

We look forward to working with the task force on ways to further improve and enhance the effectiveness of our nation's food safety system, an overarching goal that we all support. Thank you.

DR. WOTEKI: Well, thank all of you. Let me ask, first of all, do any of you, Dr. Applebaum, Ms. Donley, and Dr. Sienko, have thoughts or comments about what you have just heard from other members of the panel?

MS. DONLEY: I think it is rather interesting that we all bring our own personal experiences and personal perceptions here on this. And I just would like to make a comment, I guess from the public consumer perspective. I just -- I also would like to see, I think, that there is an opportunity here with this plan to do a risk assessment, if you would, on the whole farm -- look at the whole farm to fork continuum itself and allocate resources accordingly, and where you have an opportunity to make the most impact and the most beneficial impact to the public health and safety.

And I guess what brings me to that point were some of the comments about consumer education, public education, and what some parties view as what the public needs to know and what the public doesn't need to know. And so I really think there that if, with this vision statement being that all parties know and understand their responsibilities, they have to be given food -- because everyone understands and fulfills their responsibilities, we have to be given the complete picture.

So you can't just give a little bit here and take a little bit there. It has to be

a full disclosure by all parties.

DR. WOTEKI: Rhona.

DR. APPLEBAUM: I'm just very pleased to see -- and perhaps I'm just being a bit optimistic, but I don't think I am -- that we are not that different in terms of our focus. Obviously, I think we all do share the overarching goal. We want to enhance the safety of our food supply. We want to make it, to the extent that we can, as safe as possible. So I'm encouraged by the fact that I did not hear any major differences in terms of where we are all heading and wanting to work cooperatively to that end objective from the representatives from the public and -- the public sector as well as the consumer sector. So I am encouraged by what I have heard this morning.

DR. WOTEKI: Okay. Have any thoughts, Dr. Sienko?

DR. SIENKO: Oh, I would probably just echo that, that final comment. And I think we have a plan here. We have something to work with. And I heard a lot of shared visions and statements of purpose. And I think to go forward, we need to build on those areas where we do have a common ground, and not to destroy this, in a manner, based on those areas where we have differences.

We need to resolve our differences, and we need to discuss those. No question about that. But I think if in our discussions today, we can frame this in terms of the many areas where we want to move forward and advance the food safety system, that is in all of our benefits. And I heard a lot of that in the comments that were made.

DR. WOTEKI: Let me then open up to -- let's first start with the folks that

are seated at the table. We have got about ten minutes before our first scheduled break. And are there any initial things from the panel's points that you would like to comment on? Let's just go counterclockwise around the table. Dan Sowards.

MR. SOWARDS: Thank you. I represent AFDO, the Association of Food and Drug Officials and Texas Department of Health. AFDO will be filing some formal comments. But to echo one of the points that Dean made, we would like -- the states and locals would really like to be able to have a document, a finished document, that we could take back if we needed to to our state legislatures and say, see, this document looks at a national framework for food safety in the United States, and it points out the place that state and locals have in the overall picture of food safety in the country, and that it isn't a statement that says that the four, six, eight, ten federal agencies that have a role in food safety are the only players in food safety.

We echo the position that there should be federal oversight of state programs, strong oversight. We echo the idea that we have an overarching plan for, let's say, lab certification, not just food inspection programs, so that if this were adequately reflected in the final document, we feel that it would be a more appropriate way of saying to consumers, academia, industry, and to the states and locals, as well as the federal agencies, that this is a plan that we can use the enormous resources throughout the country in food safety to increase and reduce -- increase oversight, reduce food borne illness in this country.

Dean mentioned the -- he used the term federal system and national system.

Twice, I believe, in the document it refers to national food safety system. In early December, when we had our meeting, the task force members indicated that the we in the national food safety system includes state and local. I think that that needs to be strengthened in the document to show that the resources and the role that state and locals play out there is a very vital role, particularly in the enormous amount of resources that we have out there. And I'll stop.

DR. WOTEKI: Any other people who want to comment who are sitting here? Okay.

MS. DeWAAL: Caroline Smith DeWaal, Center for Science in the Public Interest. I'm less concerned about what is in the plan than what is not in the plan. It doesn't answer some really critical questions which were raised by the National Academy of Sciences in their report ensuring safe food, which this panel was specifically asked to answer. It doesn't tell us who is in charge of food safety. It doesn't tell us what is the best approach for managing existing and emerging hazards in the food supply. We have two different agencies that utilize two entirely different approaches.

It doesn't tell us who is accountable if things aren't done. It doesn't give us timelines for accomplishing these objectives. It doesn't unify the agency's approaches. It doesn't give us consistency in addressing hazards between different hazardous food products that are regulated by different agencies.

There is no single regulatory approach in this document that I can see. So it doesn't answer these critical questions. I guess I'm a little concerned, and there is a lot

of really good stuff in the document. And I'll try to point that out as I comment later in the day. But I'm a little concerned there is no there there, which means that these strategic plans end up in drawers all over town, and they are not acted on, they are not funded.

And without the real meat of the answer to the questions posed by the National Academy of Sciences, CSPI, and other groups on who is really in charge here, I am very concerned that this strategic plan doesn't do what it was meant to do.

DR. WOTEKI: Thank you. Does anyone on this side of the table have a comment you would like to make at this point? How about seated on this side of the room, anyone? Okay. Please go to the microphone and identify yourself.

MR. MANN: My name is Jim Mann. I am part of the industry group here. I'm in the process of writing a strategic plan for a new company. It is Health Minder. We are dedicated to safe handwashing solutions. I'm here, and I am enjoying very much what I have heard already because it helps me set some long term engineering solutions to work. We do have to find uniformity, and I like the idea of stressing science.

As I face writing my strategic plan, I am reminded of how tempting it is to want numbers on everything. Certainly, my boss wants that. But you have to look at a strategic plan as a guideline. There is another plan that is an operational plan. So I would encourage the group to think about that. And perhaps we have too many words in the vision. Maybe it should stop after the first sentence, and find the areas where the common ground is so that we can move forward on that. Thank you.

DR. WOTEKI: Good. Anyone else behind me who wants to speak?

Okay. How about on this side of the room, and at the back? Okay. Everybody wants a cup of -- okay. There is one right here.

MR. KRUEGER: Bill Krueger, with the Minnesota Department of Agriculture. And also, I am with the laboratory operations and coordination work with NFSS as well. I am the chairperson. Throughout the document, it uses the words share and coordinate information, I think for better risk assessment and so forth, and trend analysis. But we don't emphasize the mechanism to do that. And I realize this is a strategic plan, and it has go to be general in a lot of its terms.

But under the science and risk assessment goal, there is an action item that says to encourage data sharing among all relevant sources of food safety information. I don't think that encouraging sharing is strong enough. I think that we have to -- as Dean pointed out, real time is a critical word here. And I think that we have to develop standards and systems that will facilitate rapid real time sharing of information.

In the absence of that, the word sharing in that has interpretations to a lot of different people. And because the systems are in place, we have success stories like Pulsenet, but I think we need many more of those in the nation in order to have that sharing take place. So standards and systems need to be in this document somewhere.

DR. WOTEKI: Good. Thank you. We're right on time at this point for a break. Before we break, though, I want to indicate that we have asked that the temperature be reduced in this room.

(Laughter)

DR. WOTEKI: If any of you are uncomfortable, please do not feel constrained if you want to remove your jacket. You will not offend anyone. But it is really overly warm for those of us who dressed for the 20 degree temperature outside. Well anyway, we are trying to get the hotel to, if they can, reduce the temperature in this room.

And also, before we break, I wanted to introduce to you the other person who is sitting here who I did not introduce this morning, and that is Dr. Cliff Gabriel, who is seated on my left next to Susan Wayland. Dr. Gabriel is here representing the Office of Science and Technology Policy. And as many of you who are familiar with the President's Council on Food Safety know, that Dr. Neal Lane, the President's science advisor and the head of OSTP, is the cochair of the council along with Secretary Shalala and Secretary Glickman. So, Cliff, we are glad that you are here.

Anyway, we'll take a 15 minute break at this point and reconvene at 10 o'clock.

(Recess)

DR. WOTEKI: We'd like to get started with the next session, so please take your seats. Before we start, let me remind you that if you do want to be an active participant in the discussion, anticipate that you are going to have a lot to say, move up to this table. And don't feel constrained. Do find a seat at the table. Also, I'd like to remind you, before you comment, to please give your name and identify the organization that you are representing.

Susan Wayland is going to be chairing this next discussion session. So, Susan.

MS. WAYLAND: Okay. This next discussion will be a full plenary discussion about the overall framework. And I think that the panelists really gave us an excellent jump start on this session, as well as some of the comments that we received in response to the panel's comments. So I think that we already have some good ideas. And this is an opportunity for the next hour or so, or however long or however little we want to delve into this topic before we move on to sound science and risk assessment.

So this discussion will be about the overall framework. And there are three questions that you will see on your agenda. First, is the overall goal and the overall framework of the plan well focused and comprehensive? And we have heard some comments on that, and here is our opportunity to get into even more depth on that question.

The second question is what modifications would you suggest. And feel free to be very specific about the kinds of modifications that you would like to see in the draft that you have in front of you. And third, what issue or concern would your modification address?

So with those three questions in mind, we would like to open up the floor. And I think we are going to do this the same way that Dr. Woteki did the first session, which is we are going to go around the table, and then we'll go around the room, and see if they have something they would like to say. And because variety is the spice of life, we

are going to go clockwise this time, and we are going to start on this side of the table. And let me just ask if any of you would like to offer some thoughts on these three questions on the overall framework.

Okay. If not, about the back of the table or the front of the table? Any other comments? Okay. How about this side of the table? Yes, sir.

MR. STEINHOFF: I'm Steve Steinhoff with the Wisconsin Department of Agriculture Consumer Protection, a division of Food Safety. I'm also a member of the AFDO board and work on a national integrated food safety system project.

I just had a general comment about the whole document. There is the sixth point in there. It does have to do with coordination. That's fine. And I think there is a lot of good stuff in the document, science based, risk focused, very hard to argue with. The other piece that is always there, though, is limited resources. I doubt that we have all the resources we need. So prioritization of things is very, very important.

The piece that I think is missing, or it is stated there, is it has to do with agencies working with state and local governments and tribal governments. But the issue of correlation and coordination and integration in a more generic sense, you know, within the agencies, even at a federal level, if you narrow to that, just within the federal system, between agencies and within agencies, if you want to get your bang for the buck, you know, to use your limited resources wisely, to use a term I use with my children, you have to be aware of the world around you, you know, you have to know what others are doing so that you can connect with them and do things effectively so you are not wasting a lot of

effort and duplicating it, and so that you use what limited resources you have wisely.

I just think it needs to be made -- that point needs to be made more often at the beginning and throughout, and as you talk about specific action items.

MS. WAYLAND: Thank you. Yes, sir.

MR. SOWARDS: Yeah. Dan Sowards, Association of Food and Drug Officials and Texas Department of Health. To strengthen some of the statements I made earlier regarding the role of state and local, I think it would be very advantageous to all of us, considering the enormous resources that are out there at the state and local, understanding that you need adequate federal oversight, you need as uniform regulations as possible, I think the statement in one of the objectives that you have in the document regarding the examination of the laws and regulations and rules, standards, that currently exist at the state level, there are a number of gaps that we see in the federal system that by examining state and local regulations, state in particular in this instance, and seeing where certain state regulations could strengthen the national system, fill gaps in the national system -- that is an excellent point that you made there, and I think it needs to be done -- and to also mention the partnerships that could be developed with state and local.

Our resources are such that in order to strengthen the federal system, the national system, I think the federal agencies need to look at what the state and locals not only are doing, but what they are capable of doing, and saying, okay, if we can integrate those resources, both human resources and dollar resources, into this national system, then where can we most effectively our federal resources in this system because there are things

out there that the states and locals are doing.

For example, I think about in 90 percent of the inspections of non-amenable foods in our system are currently conducted by state programs, state and local, if you consider retail. That being the case, then there are obvious advantages to using those resources even more, and at the same time being able to focus the federal resources into more specific areas where risk is greatest into research and so forth.

So I think that if the document can be adjusted to include these considerations, it will be a stronger document.

MS. WAYLAND: Thank you very much. Any other comments? Yes, sir.

MR. HIGGINS: Yes. My name is Tom Higgins. I'm manager of regulatory affairs for Viskase Corporation. Viskase appreciates and thanks you for the opportunity to comment at this public meeting. Viskase is proud to participate in the development of this food safety strategic plan.

Viskase is a packaging company. And among other products, we make packaging for holding food during irradiation. And that is what I want to talk to you about today. I want to talk really about a specific action step that would improve the plan, and that action step would deal with issues of food safety that are simple. They are straightforward, but they require government review.

I'm specifically talking, in the case of our packaging, letters of no objection, which are granted on our request for the review of packaging, and particularly for the review of packaging that is for holding food during irradiation. The FDA has stopped

writing letters of no objection, and I would like this strategic plan to address that and to restore priority to letters of no objection, particularly when they are needed for food safety.

The reason I -- the reason letters of no objection are useful is that packaging and the review of this packaging is a pretty simple and straightforward process. This packaging is composed of components that are already cleared for irradiation. But it is still -- our formulas still require government review.

To give you a little more specifics, we have 13 formulations in now with the FDA on requests for a letter of no objection, and we are having difficulty getting output from this process, and that output being the letter of no objection. In March of last year, we were told that a formula that was submitted four months earlier met all requirements, that we had verbal approval on that formula, and a letter was promised, the letter of no objection, a clearance letter.

We have not received the letter. And at the end of last year, in follow-up, we found that these letters are no longer written. To make matters worse for this case, the reviewer that we have been working with has been promoted. That is not the bad part. The bad part is we are left holding the verbal approval, and the reviewer no longer has anything to do with packaging approval.

We are very troubled because of this loss of continuity, and it is unacceptable to stop issuing letters of no objection. So I would like this plan to address that and to restore priority to issuing -- writing letters of no objection.

Our dialogue went this way, and our follow-ups, this case. What is the status of our request for letters of no objection? Letters of no objection are no longer written. Are we doing something wrong? No. We want you to submit your packaging films for review. Well, why don't we get the promised letter? Well, FDA is working on a priority for food safety, and we are concentrating on petitions related to food safety and other petitions. Letters of no objection are ordinary correspondence, and we don't write ordinary correspondence any more. But these letters are related to food safety. Yeah, but they are also ordinary correspondence, and we don't write ordinary correspondence any more.

Well, should we resubmit, perhaps as a petition? Well, you can do that, but it is not going to give you what you want. We'll evaluate your request, and we'll convert it to a request for a letter of no objection. That will result in a letter of no objection, but letters of no objection are ordinary correspondence, and we no longer write ordinary correspondence. But these letters of no objection are related to food safety. Yeah, but they are ordinary correspondence, and we don't do that any more.

Well, how about premarket notification? This is the new quick way to get FDA approvals. Well, you could do that. It wouldn't give you what you want. We would evaluate your request, then we would convert it to a no objection letter request. That will result in a letter of no objection, but letters of no objection are ordinary correspondence, and we no longer write ordinary correspondence.

Well, none of this really makes sense. And so we are asking that priority to

writing letters of no objection be restored. Thank you.

MS. DEASY: -- action additional action item -- to address this?

MR. HIGGINS: Yes, I would. And I would like to see an action step to address simple, straightforward matters of regulatory concern that require government review. When you have a process like this that is government review, you have got an input, and that is our request.

MS. DEASY: You were very clear. I appreciate that. I just wanted to clarify.

MR. HIGGINS: Okay. And we would like to see the output, so you truly have a process.

MR. LEVITT: Could I just say, since that area isn't my program area, I thank you for the suggestion for the plan. We will not wait for the plan to address that. I take the point very clearly.

MR. HIGGINS: Thank you, Mr. Levitt.

MS. WAYLAND: Okay. Anybody else on this side of the table? Oh, excuse me.

MR. COLETTE: With apologies. I'm sorry that I missed my part of the cycle.

MS. WAYLAND: That's okay.

MR. COLETTE: I'm Robert Colette, with the National Fisheries Institute. And I would like to thank the government agencies for the opportunity here to have the

public comments today. NFI does plan to provide more detailed written comments before the deadline.

In regard to the particular section that we are on right now, which deals with the overall framework, I want to make a quick comment about the first question here regarding the overarching goal and the overall framework of the plan being well focused and comprehensive. We actually liked the vision statement and the overarching goal quite well. I would like to point out, however, that the vision statement uses the term farm to table preventative strategies. And I know that that is sort of the coined buzzword that is being used.

But it doesn't recognize the fact that some foods do come from other than the farm, such as the oceans. So it might be something worth considering.

MS. WAYLAND: Thank you. Okay. Any other comments from the table? Yes, Ms. DeWaal.

MS. DeWAAL: Thank you. Caroline Smith DeWaal, with the Center for Science in the Public Interest. I think one thing that is missing from this first really two paragraphs of the document is an emphasis on prevention. From the standpoint of consumers, we would really like to see food safety hazards prevented at either the far or the processing plant rather than relying on education to inform consumers that hazards exist.

So I just note that the concept -- you mentioned farm to table preventive strategies. But it doesn't follow into -- or it doesn't follow enough into the actual

overarching goal. So I think I would like to see that remedied, and I don't have a specific language on that.

I do think that the United States -- that under your section on risk management, you said the United States system for managing food safety is effective from farm to table. I think we need more than one that is effective, although one that is effective would certainly be an improvement. But I think we also need one that is coherent and one that is applied across the board on the basis of risk so that we don't have products that represent a similar hazard for consumers that are regulated under entirely different regulatory programs.

So I would like to suggest that you add to that. Maybe you could also prevention here. But the U.S. system for managing food safety focuses on prevention and is coherent, effective, and applied across the board on the basis of risk from farm to table, or from farms and sea to table. So I would just like to propose that because I think you are missing some rather critical element.

You know, the gentleman over here had a great story about bureaucratic issues. It gets worse when you actually have to deal with agencies who have multiple responsibilities for approving food safety technologies, or have duplicative responsibilities for inspecting food plants. I mean, the pizza plant is the best example there. I am still not seeing in this document the answers to the criticisms of the current system which we have laid out extensively in comments to this council.

So there are still -- we are still missing the boat on a lot of these

bureaucratic inconsistencies. Thank you.

MS. WAYLAND: Yes, ma'am.

MS. LAUTNER: I'm Beth Lautner with the National Pork Producers Council. And I would say -- one comment that I would make on the visions statement, I would agree with the visions statement, but -- and perhaps to address somewhat of what Caroline may have said, we would like to see the word education moved up after research because that is one of the focuses of when you conduct research, to put that into a technology transfer education process. And hopefully, if you do that successfully, you have to do less of the inspection enforcement part. So education, I think, is an important part.

The other comment I would like to make briefly is that I am cautiously optimistic about the strategic plan. I think -- and based on the track record already from the food safety initiative, I am very fortunate to not live in the beltway, and get an opportunity to go and see what is really happening, what is actually filtering down to the group I represent, which is producers. And I can say that we have seen some tangible benefits from the coordinated efforts that have taken place, and we see that this strategic plan provides future opportunities to continue that coordination.

And just a couple that have gotten to the producer level that we are using are the enhanced surveillance through the Foodnet, Pulsenet. That information is helpful to the producer communities to try to understand where they fit and what they need to be addressing.

We are seeing real tangible evidence of coordination on food safety research from the research -- USDA research agencies. We are seeing coordination of researchers. We are seeing more tangible information being transferred to producers there. We are seeing more cooperation from state departments of Ag, through FSIS' animal production food safety program. We are seeing -- being able to help us extend the reach of our quality assurance programs to reach more producers through those types of things.

The Partnership for Food Safety Education has been very successful. It has been a way for us as a producer group which has limited resources to be able to leverage with others, with other industry groups, consumers and government, consumer education. And we visibly have been participating in that.

I think those are all reasons, I think, for our group to be cautiously optimistic that continuing on this road with a strategic plan the components are in there. We may all have comments of things we would like to see added or worded differently. But I think for tangible things that we are seeing out, that are things that we can use to impact food safety, I think there has been successes already, and hope to build on those.

MS. WAYLAND: Great. Thank you. Yes, ma'am.

MS. DUNHAM: Yes. I'm Bernadette Dunham, with the American Veterinary Medical Association.

MS. WAYLAND: Could you go ahead and repeat your name again because the microphone was being moved at the very moment you were saying who you

were.

MS. DUNHAM: Bernadette Dunham, with the American Veterinary Medical Association. And again, we thank you for having the opportunity to say a few things while you have your whole day conference here. Generally, we do in fact support and are very pleased to see the science risk assessment based approached that you now have outlined.

At this time, one comment just to make, and that would be to see how interesting this particular proposal is going to compliment or follow the established objectives that are going to be released with the Healthy People 2010 initiative, which I think is going to come out January 25th and 28th. And I would hope that overall, as this goes forth, both of those can actually compliment each other. I think it is going to be very important that they do.

So at the moment, that is the only thing right now. Thank you.

MS. WAYLAND: Okay, great. Thank you. Any other comments from folks at the table? Yes, Ms. Donley.

MS. DONLEY: Nancy Donley, from STOP. When we submit our public comments, frankly, I am going to redraft your vision statement and make some changes. But one thing I just -- I think that when we talk education, and throughout the day, and that maybe start thinking a little bit about, is that education without behavior modification is nothing. And we have got to build in some sort of measurements of, say, what types of behaviors are actually changing.

And also, I think what we need to be looking at is remembering that there is just not one group here that needs education. Education is something that needs to be done. It is not just a consumer issue. It is an issue that needs to be done all along the line. I hear it being really focused primarily as being just something that is consumer oriented. And I think we are missing tremendous opportunities there. But we have got to be able to somehow assess how effective educational campaigns are.

And then -- I guess that is it for now. Thank you.

MS. WAYLAND: Okay. Great.

MR. SOWARDS: Yeah. This is Dan Sowards, with AFDO. I wanted to strengthen a couple of points that Caroline made, and that is the emphasis on prevention and across-the-board application of food safety measures. We have seen FSIS adopt HACCP for meat and poultry. We have seen FDA adopt HACCP for seafood then for juice, as we found problems with juice. We foresee that that may be the situation with sprouts because of the situation with sprouts.

What we would like to see is the concept of universal HACCP applied across the board to food. Now that doesn't mean that everyone should -- that laws and regulations should mandate HACCP for everyone. What it does mean is that the initial step for HACCP, that is the risk assessment, should be mandated for all foods. Then we can determine where HACCP is needed and where it's not. I think that's a concept whose time has come.

MS. WAYLAND: Thank you. The gentlemen in the back that are -- the

two gentlemen that are standing, do you want to come to the microphone?

MR. PARK: Thank you. I'm Doug Park. I'm with epidemiology and food safety at the Michigan Department of Agriculture. And I also chair a work group with the national food safety system. And I would like to make three comments regarding the overall framework on -- as represented on page 2 of the document. And I would like to echo what Dr. Sienko said earlier, and that is that the overarching goal perhaps could be embellished a little bit to include three additional items.

First of all, surveillance is not referenced, and yet you will find surveillance enumerated a couple of times within the objectives. Also, secondly, with regard to state and local agencies, we are inundated daily with complaint systems. There is a feedback loop, and the complaint systems are -- they are a great source of information and should be included here, we believe.

And then thirdly, the large amount of activity as epidemiologists that we have results in activities in outback and trace back. And that is a third item that perhaps should be looked at and included in the overarching goal. It is certainly a great impact on state and local agencies.

Secondly, in the objective two in a very important document, the initiative, and that is with regard to data collection, all of our agencies across the nation are collecting a lot of material. And perhaps that is not the greatest need. But it is sharing the information that results from that data collection. And perhaps we should look at embellishing that a little bit to say data collection and information sharing.

And then, finally, as Dr. Sam Page has eloquently pointed out many times, with regard to bioterrorism events, the statement that adverse human health outcomes should be related is certainly important. But with regard to bioterrorism, perhaps there is a need to include this as a reference, either on this line or another line within the goal. Thank you.

MS. WAYLAND: Thank you.

MR. HOLMES: My name is Scott Holmes. I am chief of the environmental health division with the local health department in Lincoln, Nebraska. I am here today as an active member of the National Association of County and City Health Officials, which represent about 3,000 local health departments.

When you eat lunch today, FDA, USDA, EPA, they did not inspect the restaurant that served your food. Local health departments did. Every place in the nation, just about, that is the case. And so when -- I realize that there are huge and critical issues, especially on the production side -- in fact, I think there have been huge steps forward in the last few years to address those, yet on the inspection side, there are still some major issues to be addressed there.

But my comments are really related to the vision statement. And I think Doug touched on the overarching goal in the vision statement. The word surveillance is used. In the overarching goal, surveillance is not used. Just a little nuance there, but I think there has been a lot of effort put into this plan, and those sort of things are going to happen.

But perhaps the question that comes to mind, is this a federal food safety plan or is this a national food safety plan -- I think that comment was made before. And I don't know that we have the answer to that yet. I do realize that the federal strategic initiative has to focus on federal government. But a seamless system, as identified, has to include state and local government. And I would suggest the vision statement could be broadened to add a statement that it views state and local food agencies as full partners in the seamless system. That simple statement then makes the rest of the document work for state locals for the most part.

We can pick and nitpick. But you don't mention it there, and then it's touched on in various areas throughout the document. I don't see why it isn't just said up front in the vision statement. And that's all my comments.

MS. WAYLAND: Thank you very much.

MR. OSAKI: My name is Carl Osaki. I just retired last year as the chief of environmental health with the Seattle King County Department of Public Health. And I have had a few episodes that I have had a chance to work in real time, Jack-in-the-Box and Autwala (phonetic) outbreak regarding e. coli. I am also a clinical social professor at the University of Washington in the School of Public Health and Community Medicine, where we teach food safety to students.

By my reason for being here really is as a member of the Washington State Board of Health, where we make policy regarding health for the state of Washington citizens, including food safety. And as a matter of fact, just within the last six months, we

have passed two food safety regulations in the state of Washington as a state board of health, not because the federal government told us to do so, but we felt it was the right thing to do. One is that we are requiring 30 minutes of interactive training and education for all food workers in our state. And another had to do with ensuring that any restaurant that serves unpasteurized juice notifies all of its consumers that it is unpasteurized.

I'm going to work backwards here and say that on the overarching goal, I would, one, make a suggestion, and that is that you talk about coordinated regulation, inspection, et cetera. I would recommend that we say something about coordinated policy development as well. And the reason I say that is, again, in the state of Washington, we have a board of health. And I think about half of the states in the nation have boards of health that define food policy, develop regulations. The rest of them default, I think, to the state legislature for food safety regulations.

I am not accountable to any organization at the federal level as a Washington state board of health member to set food state policy. However, it would be nice if in fact we had some kind of continuity in terms of policy development from the local to the state to the federal government. It has to have some kind of a flow of accountability or some incentives so an objective, for example, might be something that creates an incentive for state and local health departments for developing policy that is consistent, for example, maybe a certification program for state and local health departments upon -- using agreed upon performance standards, and actually tie it in with some kind of monies that are available from the federal government to do so.

So I would suggest that policy development, along with incentives, be a part of the strategic plan to make it work. Thank you.

MS. WAYLAND: Thank you very much.

MS. BILLAUER: Thank you. My name is Barbara Billauer. I am with the Association of Environmental Health Academic programs, and I want to retake off what Ms. Donley said. Education is not just important for the consumer; it is important for the people who are involved in food safety. We are talking about food safety today, but what about food safety tomorrow? Who is training the future food safety people?

And that includes not just the inspectors, but the people in industry who should be doing internal safeguards, and the people in service institutions who should be making sure that there is internal compliance with internal policy that might be generated as a result of a meeting like this, but is useless if it is not part of the corporate culture. And so where most corporations now have OSHA or EPA assigned health and safety people, I'd like to see in the future that we have that same commitment in food safety. But then the question is who is training them and what is the training.

At this moment, most states will hire inspectors -- or may hire inspectors; they are not required to -- and food safety or other environmental health safety professionals who are not required to attend an accredited college with a program in environmental health. That means that I can make sure or feel comfortable that my manicurist has some degree of certification, but the person in my state may not have that same level of oversight.

And so I would like to call up this council to do three things: one, to support the National Accreditation Council on Environmental Health's role as a federally approved accrediting agency so we can make sure that those programs that exist in the country do have an approved standard in environmental health programs and curriculums. And the second thing is I would like to see a commitment to the future of students who will end up in the field of environmental health, and that is in the form of scholarships, internships, working for people like yourselves so that these young students can see the way we hope things should be done, as well as -- and this is a sad fact, that the number of students in environmental health programs has been declining over the past five years.

That means that the field is not perceived as being glamorous or important, and that can be done through public relations and through a commitment by the federal government to impress upon the country that we need to appropriately train people that can carry out this mandate. Thank you.

MS. WAYLAND: Now were there any other comments? Let me just -- yes.

MR. MANN: Jim Mann, Health Minder. I just wanted to -- I was looking for an appropriate place to put the potential addition here that industry is the primary person responsible for food safety. From a strategic point of view, I find that helpful to be acknowledged somewhere here, that we are trying to help them. Perhaps by the end of the day, I'll come up with some wording. But I just wanted to make that point. Thank you.

MS. WAYLAND: Thank you. How about from behind here? Yes, sir.

MR. GARCIA: I am Dr. Genaro Garcia. I represent the Pan American Organization. Briefly, I want to thank you, you all, USDA, for inviting us to this important forum. I just came two weeks ago to Washington. I was -- Barbados, and I came just about two weeks ago with my family, just am glad to be here.

I have probably three specific comments, information to the mission statement and the overarching goal. I endorse the motion on -- board of education to -- the orientation after -- right after research. I would say -- I would suggest to put it after, immediately after, surveillance because -- the reason being that surveillance and research are basically all the same thing. Research studies are a part of surveillance. Surveillance and research will provide the information to elaborate the educational tool and different levels and targets to the different people. That is one suggestion.

The second one is in the overarching goal is reducing the prevalence of food borne hazards and will include after food borne the word -- two words, food borne -- before, I'm sorry -- prevalence of old and new food borne hazard, the reason being that there is a characterization already being done at the -- characterization of the old food borne hazard and the new one. And that characterization is already being done; information is available. Therefore, I believe that is important.

I also endorse the inclusion of the epidemiological surveillance in the overarching goal. The reason has been explained by various of the speakers. But I want to emphasize that the epidemiological characterization is very important given the scarcity

of resource and the need to prioritize in the explanation.

I believe that the information was at the National level and at the local level, and I would give more importance to the local level analysis of the information, the epidemiological information available in order to do the epidemiological characterization of risk according to the epidemiological trends, what are the food borne more likely implicated associated with food borne outbreak and -- what are the critical control point violation.

All this information may be available, and that has to be analyzed in order to prepare a profile, epidemiological profile, at the local level in order to prioritize the industrial strategic plan and in the uses of resources, and therefore getting a more cost effective and cost benefit in the smaller resources.

In relation to education, again, going through what -- I know we are going to touch on the risk communication. But I didn't see the word there of universities, college, or that has been mentioned. And I believe there is a really having the opportunity to be in Davis in California in the early 80s, I know that all the extension services at the university have no material education. And I believe they need to particularly compile all this information and -- probably standardize and use the information that is already available.

Thank you very much.

MS. WAYLAND: Thank you. Let me see if there is anyone else from behind here before I turn to you.

MS. MURANO: Thank you. Elsa Murano. I am associate professor of food and microbiology at Texas A&M University and director for the Center of Food Safety at Texas A&M University.

I wanted to start off by saying that I agree wholeheartedly with Nancy Donley about the vision statement. I think it definitely needs a lot of rewrite. And I agree with what you said as far as what implications it might have on the minds of consumers or other groups when they read it and maybe get the wrong impression. But my comment has to do with I love the fact that this strategy or strategic plan is science based.

It is a term that I think we should all appreciate. And for that reason, I would like to really emphasize that we include the word science as much as possible throughout the document. It is here or there, but perhaps not in there as much as it should be. On the first objective, for instance, or the first goal, I would love to see the scientific community's input be showcased as a place where information would be gathered in terms of research.

That has a lot to do with the way that we have viewed food safety over the last few years. We tend to be very reactive, even in terms of funding. Listeria, e.coli 0157:H7 are the bugs of the moment, so all of the funding goes to those. And we talk about looking at emerging threats, but do we really look at emerging threats, or are we always, because of what is in the news, always looking to work on those threats that are right now and important.

I would suggest to you that by having the scientific community be an

integral part of the decision making process, is that we will include such things as looking at the microbial ecology and factors, environmental and otherwise, that may promote the emergence of new food safety threats. And that is something that I really didn't see in here specified as well as it should be.

It talks a lot about surveillance, and surveillance -- I will disagree with my friend from PAHO. Surveillance and research are not the same thing. Certainly, surveillance is something, as we know, that provides the data on perhaps where we should be focusing our resources in a way. But research, especially basic research, is really where we get our focus for what may be coming down the pike. Otherwise, we will continue to be reactive, and we cannot afford to be reactive any more. Thank you.

MS. WAYLAND: Thank you. Yes, sir.

MR. DOOLEY: I'm Lou Dooley, with the Southwest Washington Health District in the great state of Washington, the other Washington, and also representing the National Association of City and County Health Officials. I want to make a couple of comments about the overall framework of the plan and just -- and think that we need to strengthen our system to get to what Scott shared with us a little bit as where the rubber meets the road. We need to be able to make the system stronger out there where we are doing the inspections and are doing the leg work that is necessary.

I agree with the comments of the former -- of the person just before me. However, we need to be able to communicate those issues to the people who are affected and those that are the consumers of the products that we inspect or the food service

establishments that we interact with. And we need to be able to communicate to them. And if we start trying to talk about the difference between research and surveillance, we are never going to be able to meet those needs because we have got to be able to talk to them at a level that they understand. And we are just poor folks down there at the local level, and we need to understand what the regulations are in black and white and not be able to get lost in all of the rhetoric, or not -- I don't mean that as rhetoric, but get lost in all of the big words of education.

We have a great system in the state of Washington, but we approach public health as a four legged stool. It is academia, particularly the University of Washington and the state systems, the state board of health, the state department of health, and local all working together. And we do that because we can communicate together.

Now our problems are very large. And what we are trying to do address with this system is very, very large. The states and locals can't get their arms around the issues that we see or that we all agree are some of the problems. Imports, exports, just the coordination of issues at the federal level is more than the federal level can deal with. When we get down to it, we need to get down to where -- to the implementations of the rules and the standards.

About the vision and the goal, I feel strongly that we do need to set a vision that is out there beyond where we are at right now. We have gotten into problems in this country because we have been able -- because we have always boxed things in. And we need to look beyond it. And that is what a vision statement is. We are looking

out there, is this somewhere we want to be.

Now maybe we need to articulate that a little bit differently because I agree, we can't put the public to sleep and say that we have got a great system. But we have to have it out there beyond where we are at right now. It has to be a vision or else call it something else. But if we are going to call it a vision, it has to be out there, something that we are striving to get to.

We have to have the capacity to respond. The local level, the state level, can't reasonably set risk focused science based standards and issues. We have to look to the federal level to do that because that is where the science is. That is where those standards are set, on a national basis. And we can't do that at the local level. We need to look to you to do that. We are going to implement them down where the rubber meets the road.

You can really help us in doing that. The communication is really the success, or really the key to success, of a lot of this. We have had more than our share of issues in the state of Washington. Carl talked about the e. coli and the odwalla issues. We also have had just some issues with e. coli in a swimming lake where we had 34 cases 0157:H7 in a lake. We were able to respond to those very quickly and prevent people from becoming more ill, or more people from becoming ill, because we could communicate.

We had a federal system that has been implemented in the state of Washington that allowed us to communicate with CDC and every other health district that

was participating in the pilot project, where we put a health alert network across the country. That communication opened up the ability for us to be effective and prevent illnesses from growing. We responded well, and it was through the coordination of the resources from the federal level to the local level. And we need to clarify who, what, where, and when -- what our rules and expectations are. And we can best do that in a document like this.

We appreciate the opportunity to testify and give some input into this. We need to all work together as partners and work on the successes rather than just relying on the frustrations of what we have done in the past. When we do that, we get beyond the issues and start to look at emerging things. But we also can't lose face -- or lose sight of the fact that we have diseases, communicable diseases, which we thought were controlled in the past but are coming back because we have been off looking for new things and new emerging problems.

But we have problems like polio and tuberculosis, things coming back that we thought were controlled. And we can't lose sight of that either.

MS. WAYLAND: Thank you very much.

MS. STEVENS: Jennifer Stevens, with the American Academy of Pediatrics, Washington office. I just wanted to highlight one sentence from the vision statement: "We are vigilant to new and emerging threats and consider the needs of vulnerable populations." I think it is important to highlight the needs of vulnerable populations right up front, especially infants and children. Obviously, not all consumers

are affected equally by food borne pathogens, pesticides, and other threats in the food system.

However, I would -- I think the academy would like to see the impact on vulnerable populations as an issue that is more thoroughly discussed throughout the document, not solely in the vision statement. I think it is important that it is in the vision statement, that it guides -- it is a principle that guides this process. But I think it also needs to be brought up more frequently in some of the action items and some of the objectives.

MS. WAYLAND: Thank you very much. Anybody from this side of the room? I feel like I have neglected you all over here. Any comments anyone would like to come up and make? Am I missing anyone behind me? Yes, sir.

MR. LERMAN: Yes, Dion Lerman. I work at Drexel University in Philadelphia in a program called Food Safety First, where my emphasis is on training food safe -- or food handlers, the people who actually cook the food, as one of our earlier commenters mentioned. And I did notice that they are in fact absent from the list of people that get cited in the document. And I would like to suggest that they deserve some consideration.

My further comments may be a little odd, given that I am speaking -- that I am an educator, and that is what I do. But I do think that the plan does need to focus much more on prevention further down the line. Educating the food handlers and consumers is an important step, but they need to have food that requires less intervention.

Let's put it that way.

And I think, for instance, of another product of this group, which is the egg safety plan that one of the task forces put together, which is based largely on an extremely successful plan in Pennsylvania, the PEQAP plan that helped pioneer farm based intervention strategies that has been extremely successful, and would recommend -- commend that to people.

Also, I would like to comment on things that other people have said, our friend from Texas A&M, specifically about science and the science basis, which I think is one of the things that makes the current food safety programs so strong and impressive. But I would also like to sound a word of caution here. When the phrase "sound science" gets used, who says what science is sound? Science is a moving target. And what we know today is different than what we knew yesterday; what we know tomorrow will be even broader. And if we base our ideas on sound science only on what is known, then we are constantly reacting. And as Ms. Murano said, we need to be proactive in our science and constantly looking for the new challenges, the emerging problems, and for creative responses to that.

And finally, that these efforts, as with all of our efforts, need to be transparent and independent. The public is demanding transparency, and it is being codified in Europe right now. I think it is an excellent thing. And if we try to fight it, we are going to find ourselves in a lot of trouble because I do think that ultimately we are all here, all of us, to build that partnership that we keep talking about.

We do have, in fact, common goals. We may have different priorities, but we all have common goals. And we need to remember that.

MS. WAYLAND: Thank you very much. Okay. Are there any other comments? Is there anyone who has an opinion, a comment, reaction to something that someone else has said or your own comment that you haven't been able to make yet on the vision statement? Yes, sir.

MR. GREENBLAT: Good morning. My name is Jessie Greenblat. I worked as a state epidemiologist with New Hampshire Department of Health and Human Services. I'm also here representing the Council of State and Territorial Epidemiologists, a network of approximately 400 epidemiologists at state and local health departments throughout the nation investigating food borne illness.

I wanted to make a few comments with regard to what has already been said. First of all, I do want to support a number -- the statement that have been made by a number of individuals regarding the importance of surveillance in the overarching goal statement. And we also feel that it is very important to add that as well to the statement.

As well, we wanted just to ask that in the first iteration of the strategic plans with the five different goals that were mentioned, or objectives that were mentioned, that have now become three, surveillance was in particular one of those original five. In the process of making it -- of going to the three, surveillance -- and the word surveillance occurs in a number of different areas throughout the document. We feel it is important to make sure that those are well defined.

I'm not sure surveillance is actually a very public term which a lot of the public might understand very well, unless we specifically state every time that it is surveillance for human health conditions. That is different from surveillance in laboratory mechanisms for surveillance of pathogens in food or surveillance as might be defined in many other ways by different groups who are involved. I think all of us sitting here understand that. But again, I am concerned about the translation to the public setting, what surveillance means and defining that.

In addition, I would also like to suggest that one of the action items be a clear understanding and agreement about what risk means. We all mention risk management, risk assessment. Risk is one of the more common words throughout this document. However, I think we need to agree, does risk mean that the priority conditions are those that occur to the greatest extent. Is salmonella or campylobacter, because it has -- there more condition -- more people becoming ill with that disease of higher risk than something such as e. coli, which has a greater mortality associated with it? So I think we need to agree in an action step exactly what do we mean by risk as a concept.

In addition, I wanted to suggest that one thing that we find missing in the plan is the translation of surveillance information to investigation and action. There is an awareness in the plan of the importance of responding to food borne outbreaks of illness. And there is a recognition that surveillance is important. What we are missing is the translation of that surveillance information into action and potentially into regulatory action as well.

So, for instance, what we see as a regular occurrence is we'll find ten cases of salmonella occurring throughout the state of New Hampshire. And it is depending on how aggressively we pursue those independent reports, how aggressively we pursue the laboratory methods to characterize them, to do the DNA fingerprinting, sometimes, whether or not recognize it as an outbreak or not. So we want to be able to place that concept in there.

I may also -- I was thinking of making some of these comments later. But seeing as everybody was standing up, I felt it was important to also make that mention here as well. And I think I'll end with that. Thank you.

MS. WAYLAND: Thank you. Now are there any other comments? I know that -- yes, sir?

MR. HIRSCH: I'm Martin Hirsch, the manager of the French Food Safety Agency. If you'll allow me, I will say a few words because I think it is very interesting to see that different countries have the same concerns at this period. And I was very interested to -- listening to the opinion which was expressed this morning, and maybe to give you a few words about our experience in France and in Europe.

As you know, in France, we created the Food Safety Agency ten months ago, and there is a draft in Europe at the European level to create a food safety agency. And I think that the reason why we did that in France and in Europe -- some reasons which were summarized this morning. The first reason is the new attitude of consumers, which are more demanding of more safety. This may be the same attitude, the same

behavior that had consumers with malpractice, with -- diseases.

It is now a big fear, a big concern about the food safety, and some problems that we could tolerate a few years ago are not tolerated, not accepted now. And they want more safety. They want also more information. And they want also to understand how is the decision making process.

The second fact is that in Europe, like here, we are facing emerging risk. And the question is how we can be ready when these emerging factors are coming with new infectious diseases like BSE or new interrogation about some chemical products.

And the third reason is that we faced a major crisis with a huge impact on the economy and on the organization of the production. In some cases, there is no direct relationship between the crisis and its impact and the real risk. Sometimes we act to underreact, sometimes to react more, and to more -- because we were in a system in which we were not prepared to these events.

That is on this kind of analysis that we tried to reform our system in France. And I think it is the same way it is done on the European level now.

What are these principles? The first principle was to create an organization based on science with the responsibility for risk assessment on the global food chain, and then for all products which are animal products, which are vegetable products, which are drinking water, and from upstream to downstream towards a scientific community, which can be mobilized for this kind of problem.

The second principle was to have -- is to compare two different systems,

this system with risk assessment, a second system with risk management. And if we organized a very close relationship between both of them in terms of exchange of information, as was underlined by some participants this morning, it is absolutely crucial that information at good time can circulate between all the people involved in that.

We tried to organize two different chains of responsibility, one responsibility for the risk assessment, independent of economic interests, independent of political interests, and to have -- to create a chain of risk responsibility for the risk management.

With the third principle, we just tried to make as transparency as we can -- as many transparencies as we can. And in the process, we tried to make that every scientific opinion expressed on the problem is systematically published so that the people and the consumers can say on which ground a decision can be taken. When sometimes you have -- it was, I think, underlined to take into account the scientific evidence, but sometimes also just the scientific uncertainties.

And sometimes the science doesn't give you every answer you would like to have. And so in the case, you have to take what the science can say and what it can't say, but also other factors, such as what are we able to do every level of the administrative and the economic action, and what are the consequences of the regulation on the new standards.

I think that addressing -- to seize it, we are facing exactly the same problems. And we don't know what is in terms of organization. But we see that there are

a few principles which can be adapted according to what are the administrative organizations, what is the political organization. And you can't have a single model which can be applied everywhere in the world. But you can have some common principles. And I listened to things this morning which shows that some of these principles are the same in different countries. Thank you very much.

MS. WAYLAND: Thank you very much. I think we have heard a lot of different perspectives this morning and tremendously valuable comments. I would like to turn it over right now to Dr. Woteki because I think she has some questions of you based upon what we have heard this morning.

DR. WOTEKI: Yes. Thank you, Susan. I first of all want to say how impressed I am by, Dr. Hirsch, your remarks, and also by the fact that there are representatives here from many different countries. Clearly, our neighbors, Canada and Mexico, are well represented here. But there are personnel not only from the World Health Organization and PAHO, but also from many embassies, both in the western hemisphere as well as from around the world.

So I think that is an indication, as you said, of the importance of food safety in many different countries. And also, I think, a reflection of the fact that so many of us are either completing reorganizations of our federal or national approaches to assuring food safety, or are contemplating such changes. So we -- you are good to remind us that similar discussions are occurring in many different countries.

Also, I have been quite impressed by the statements that we have heard so

far from the many representatives that are here from state and local governments. And there were two issues that came up in the sessions we have had so far this morning that I wanted to ask some questions back to you about. The first is that there are several comments that were made about is this a federal plan, or is this a national plan. And certainly from the task force's perspective, we view this plan as clearly representing the needs and the interest of a overall federal, state, local, and tribal government approach towards assuring food safety.

So from our perspective, this has to be a national plan. But also, because of the charge that was given to us by the President, we also need to be looking at the roles and responsibilities of the federal agencies and how we can better work with our state, local, and tribal counterparts. So at least my take away from the discussion so far has been that we need to do a better articulation of that focus.

But I would certainly like to hear if there are -- those of you who have not spoken so far, or those of you who have on this issue, what you see as the specific things that we should do in this plan's -- at this point, we are talking about the overall framework. But also, as we get into the discussions later on today, what are the specific changes that you think need to be made in the phrasing of the objectives and the action items?

So let me just ask at this point, is there anyone who would like to address the question since we are now talking about the overall framework of federal versus national plan, and specific changes that you think need to be made at the framework level.

MR. SOWARDS: Cathy, one of the things that -- this is Dan Sowards, AFDO. One of the things that I tried to articulate earlier was that by looking at it as a national plan and seeing where the resources are and the abilities are at the state and local area, that can help the federal agencies concentrate on where they need to most in particular to use their resources.

But at the same time, one of the things that I didn't articulate is how that plays into the framework of the strategy. And that is by looking at what the states and locals are doing and are able to do, or could do, then the federal agencies across those agencies can see more clearly, I think, where they can use their resources and not really duplicate what each other is doing.

An example that others have given over the last several years in particular would be the federally inspected meat facility that does non-meat products. I mean, there is absolutely reason to have two agencies doing an inspection in the facility. So -- and at the same time, I think you can also look at the distribution of products, whether they are FDA distributed products or FSIS distributed products.

If there is certain information, certain assurances of safety that the federal agencies need, you already have state and local folks that are going into these facilities and doing inspections, obviously, for a number of reasons. And I think it would facilitate an overall national plan and more concentration on resources, on risk, if there is this specific information, specific guarantee that the federal agencies need of the continuing safety of the products once they leave the processing plant. And if there is need for additional

training, let's say, of state and local investigators, that that be one of the considerations that the federal agencies use in determining where their resources can most best be used.

DR. WOTEKI: So I would take it then that you would suggest that there be an action item that would be an assessment of resources, federal, state, and local, within the context of regulatory and statutory authorities, and then to identify ways that we could make better use of those resources and remove impediments to that.

MR. SOWARDS: Correct. In fact, one of the resource assessments that has been suggested and actually worked on by one of the national workgroups will address the capacity and the resources and the laws and regulations that are out there right now, that perhaps we don't have a total picture of at the present time.

DR. WOTEKI: Okay. Joe?

MR. LEVITT: If I could just follow up on that. As we look at this in terms of even more strongly covering the state and local governments in your contributions, are there things that should be added or included in here that would address ways to strengthen the state and local programs, whether it is in infrastructure or training or competencies or consistency or anything like that, that we could help, as you said, you can take back in the different states and say, yes, we need to do some upgrading here, too?

MR. SOWARDS: There are two or three issues that you have addressed in the document, but not strongly addressed, and I think perhaps a rewording of an action item or strengthening of an action item. And they are oversight, federal oversight of state, state oversight of local. I think that needs to be strengthened because if consumers are out

there and are fearful that if anything is given up by the federal government to state and local, that it will weaken the system.

I think there needs to be strong oversight there to ensure that whatever the state and locals are doing is equivalent to what is envisioned of the federal government doing. I think the other issue is what you have said about looking at the laws and regulations, standards, that are currently at the local and state level that may fill gaps and are strengthening what you have at the national level. I think that needs to be reinforced.

And I think the third thing would be the resource assessment. And that is you need a strong statement in there about doing the resource assessment in determining where the resources are, and therefore determining how best federal resources can be used.

DR. WOTEKI: Okay. Stu?

MR. RICHARDSON: Stuart Richardson, California Department of Health Services. And just to add on a few comments, when I got up here I had some ideas that Dan expanded on. But why the discussion of the federal system, the national system, is important, as the federal ideas occur and change, there is significant impact to the locals, as everyone would expect.

We talked about the large resources that are out there already. It seems to me that the add on items here are objectives and action items dealing with not only assessing and trying to find out what is going on, but really marshalling and mobilizing all of our joint resources to those highest priority risk identified issues.

One of the statements which is in the document which I think is very good is another challenge is to allocate resources where risks are high. It can't be done only by a federal system by itself or a national system. We will never have enough resources collectively for all of us to do all of the things we think we might need to do at all levels of priority. So it is essential that in the document, past the overarching philosophy, which I think should encompass some of this thought, but in those goals, that there be specific objectives and action items in all three areas dealing with mobilizing, marshalling, or action statements that say that we are going to reach out and not only identify the resources, but we are going to build them into a system and utilize them so that those resources are going to the highest priority as well.

MS. DeWAAL: This is Caroline Smith DeWaal, with the Center for Science in the Public Interest. I think the comments and what we are hearing from the states is very good. But I want to caution the panel that it is not acceptable from a consumer standpoint to have the federal government simply turn over parts of its responsibility for food safety to the states.

There are issues around state regulation that, you know, are just there. There is a very close at times political relationship between the regulated entity and potentially the governor, who may impact how a particular plant is being regulated. We have tremendous concerns about that. We are also very concerned that the state budgets cannot -- can vary from year to year. And we can find food safety inspections being dramatically cut back in a year based on a particularly tight budget that year at the state

level.

That is not a reliable system. We need -- at the same time, the states have jobs which they are already responsible for, things like we have heard a number of times today. They have primary responsibility for inspecting restaurants, hospitals, schools, nursing homes, and other places where food is prepared. And in many instances -- we have done a study on this. Those jobs are not being adequately done today.

So I think it is very important. I recognize the tremendous job the state has done in filling in the gaps, particularly in FDA's inspection program. But that is not the system of the future. The system of the future is one where we need a uniform, across the board inspection program that consumers can rely on with the states knowing what their jobs are and knowing what their responsibilities are so they can apply their resources appropriately so they can budget appropriately.

And I have tremendous concern. While I support entirely the work the states are doing on food safety, we need a coherent federal system into which they know where they can best do the job.

DR. WOTEKI: Thank you. In the interests of keeping us on time, since we have such a busy agenda today, I would like to then pose a second question and ask people if in the written comments that you will submit, you could pay some attention to this question. And a number of commenters have talked about the lack of measurable outcomes.

One of the things we are particularly interested in hearing from you would

be what concrete outcome measures would be appropriate for the overall goal for this plan. Certainly, as our task force will be moving after this meeting, one of the things that we have set for ourselves to do is to develop the action plan that would essentially go along with the strategic plan, and that action plan would have measurable performance objectives. It would have a timetable associated with it. But at the level that we're talking about right now, which is, you know, the overall, overarching goal, are there some performance measures that you think would be appropriate to use in evaluating our progress towards that goal?

So we would particularly be interested in your comments on that. And I might say, as we go through the rest of the discussion today, if any of you on the action items, objectives, or the specific goals as we are going through have got recommendations for performance measures for any of those, we would also welcome your comments on that. Okay. Thank you, Susan.

MS. WAYLAND: Thank you.

DR. WOTEKI: The next discussion is going to be moderated by Dr. Gabriel.

DR. GABRIEL: Thank you, Cathy. It is my privilege to talk about some science, one of my favorite topics. Clearly, the National Academy of Sciences, many of the organizations, individuals have really driven this message home to us loud and clear that the food safety system needs to be based on good science, sound science, credible science, and also on a good system of risk assessment. And this goal, objective and

objectives and action items really is our attempt to try to get to that.

So I guess what I would like to do is follow suit with Susan's approach here, go around the table, and then go around the room and get your comments. So why don't we start over here?

MS. SOSA: -- right now. Are we going to address all of our comments with regard to each of the objectives and action items at this time?

DR. GABRIEL: I think that is the best way to go.

MS. SOSA: Okay. One of my concerns --

DR. WOTEKI: Can you identify yourself, please?

MS. SOSA: I'm sorry. My name is Meryl Sosa, and I representing Food Animal Concerns Trust. One of the main concerns that I have about the document overall, and particularly objective three, is that I wondered why the focus under the final action item is limited to water used for food production and processing. And I wondered what about water use for humans. And it would seem that safe water is an important area to be considered in this area.

And one of the things that concerns me is I recognize that EPA is represented in the pesticide area. But there is no representation with regard to animal waste. And our organization views this as being part of the farm to table continuum. And, for example, objective three mentions animal feed. Well, one of the items that is often included in animal feed is animal waste, for example, poultry litter or things like that.

And we have a concern that there are no regulations of this whatsoever.

And even in the guidance manual and the example permit for concentrated animal feeding operations, the review draft that was issued in August of 1999, there is no mention of this at all. And that has to be considered because studies have shown that antibiotic resistance can be transferred through, for certain, poultry litter. And therefore, this scenario is relevant to consumer health.

So we feel that that is a really big consideration. And also, we know from studies that e. coli 0157:H7 can survive for substantial periods in the soil. And we don't know what impact that has on our crops or on the water because it can filter through into the ground water, which is also not covered by the manual. So we feel that animal waste is a big area, and it is not addressed in this document at all. So we would like to see that be considered.

The other thing that we would like to find out is how transparent the process is going to be as we progress because we would like to know whether consumer groups are going to be able to provide input regarding research needs and gaps as they perceive them, and not just as perhaps regulators and academics and industry perceive them because we may not have the funding to be able to do the research. But we would like to see some areas that we feel are important be addressed by research. And we would like to know how we can be included in that process.

And we would just like to note that there were apparently two meetings in December for, I guess, professional organizations and industry organizations, and consumer groups were not brought into that forum. And we are a little concerned about

that because last summer we were brought in, and everybody had an opportunity to speak to the issues. But then, in December, we were somehow excluded from that, those considerations. And there wasn't a separate meeting held for us or anything like that.

So we just kind of would like to know where do we fit within all of these considerations.

DR. GABRIEL: That's a lot. No. As far as -- I can address some of these, I think. Susan might want to touch on some of the EPA's role in all of this concerning water and pesticides, et cetera. As far as consumer input into the overall setting of the research agenda, clearly there is going to be an opportunity for that at multiple levels. But I think one of the -- the main mechanisms will be through the Joint Instituted for Crusade to Research when that eventually gets up and running.

We are making a lot of progress identifying staff, space, et cetera. It has been a bit slow going. But I think we are moving a lot closer now to getting this up and running. There will be an advisory mechanism associated, you know, with that joint institute. So there will clearly be an opportunity there.

As far as the consultations that went on in December, actually, the very first one that we had was with a small number of consumer groups. These groups -- these meetings were not as large as we would like, but we felt it important to reach out that time in a fairly quick and a rapid turnaround kind of way to get, you know, some initial input on the plan as it currently stood.

So there was some consumer input during that consultation process. We

appreciate your comment.

MS. WAYLAND: Let me just add that I think your comments are quite fair and valid. I want to emphasize that in EPA, the Office of Water and the Office of Research and Development are fully participating, as well as my office, which is primarily focused on pesticides. And we will look to your comments and the other comments we get here to make sure that the water elements, the animal waste elements that EPA is involved in as well as the research get the amount of emphasis that they need. So thank you for your comments.

DR. GABRIEL: Okay. Any other comments from this side of the table, down at the end?

MR. COLETTE: Robert Colette, National Fisheries Institute. This is sort of a general comment, and it has to do with a number of the objectives under the science and risk assessment goal. There are a couple of words that I think need to -- that are used in some places that probably need to be repeated in other of the objectives.

For instance, the word coordination appears in the action item under objective one. But I think coordination between the various federal agencies and as we have talked about at other levels of government and interaction with the scientific communities and so on, with all of that interaction taking place, I think there needs to be a stronger emphasis on coordination. And that should begin with the federal agencies. You know, we still do see inconsistencies in what is considered to be sound science and approaches to risk assessment. And there needs to be sort of defining of roles and a

coordination of those activities.

And I think we also -- and it may be in here. Maybe I have missed it. But I think there needs to be a recognition of the importance of addressing these issues, not only through the scientific community within the government agencies, but also outside of the government. I think that many times the government can be enhanced in their efforts by seeking out scientific input from the general scientific community at large. And I don't really see that emphasize here in a lot of these objectives under the science and risk assessment goal.

DR. GABRIEL: Thank you. Any more on this side? Back? Take them in order. The gentleman in the middle.

MR. GIBSON: Okay. Usually ladies first, but I'll go ahead. I am Jerry Gibson. I am director of disease control, Bureau of Disease Control, at the South Carolina Department of Health and Environment. So I'm a state health worker. I also am a member of the Council of State Enterobacterial (phonetic) Epidemiologists, which is a private organization of people who do epidemiology and disease control at the state and big city level.

I was planning on giving more of a comment this afternoon on the risk management section. But I'd like to make a brief and perhaps a little bit controversial comment in this section, too. And it has to do with objective three, develop and implement the risk based problem solving research agenda, and with the second action item, using risk analysis to identify gaps and establish priorities. And I see missing from

the somewhat detailed list of areas to work on here the issue of antibiotic use in animal feeds for growth promotion.

That might not be the right place to talk about it, but I think it is a real concern, as we all know that many antibiotics, some that are in use for treating human illnesses and some that are related to them, are widely used as growth promoters around the world. And they could have a big economic value for food production, but we are seeing increasingly that they are having an impact on the availability of antibiotics to treat human illnesses.

And I'll cite just one example because it is sort of striking, and that is the use for awhile of an antibiotic called virginiamycin for -- which is not used in human production, but is related to a brand new antibiotic called Synercid, which has been introduced to deal with some issues of extremely resistant enterococci and staphylococci. And there is a concern that this new antibiotic, Snyercid, is going to be almost unusable by the time it hits the market because there is some very good evidence that this is related to the use of a related antibiotic in animal feeds.

And I think that as the problem of our losing antibiotics for human treatment becomes greater and greater, we will have to reevaluate the cost benefit of the use of antibiotics that are related to human treatment antibiotics in animal feeds for growth promotion. And I suggest at least some reconsideration specifically of that cost effectiveness balance.

DR. GABRIEL: Thank you. Next.

MS. LAUTNER: Beth Lautner, National Pork Producers Council. My comments are related to making sure that there is not a loss of emphasis on research. When there were five goals, there was a specific one that had quite a bit of details about research. We want to be sure that that is not lost in this process.

I had two comments, specific comments, about objective one and objective three. In objective one, as you talk about expanded surveillance and rigorous assessments of risk, strengthening the scientific basis is going to be dependent on research as well. So I think it would be appropriate to insert expanded research and surveillance. Specifically with objective three, as we talk about -- I think it is a very good objective on our problem solving research agenda.

But I would put forward that I think it is exceedingly important that to develop this coordinated unified research agenda, that we have a comprehensive food safety research database. And I think that a comprehensive food safety research database is absolutely critical. And it should be at the very least an action item. But I think it would be preferable to have it as a specific objective, recognizing there is some work in this way.

But comprehensive food safety research database is a critical part of developing the research agenda. It does a lot of things. It identifies research voids. It links researchers together, avoids duplication, speeds technology transfer, and provides opportunities for groups of researchers to be identified to help with specific targeted projects.

I also would add as an action to develop in addition to the research database, to develop a framework in which to measure this research progress, to measure your progress on your unified research agenda, and the ability to communicate this progress to the stakeholders. I think that is an exceedingly important point that many times people are not recognizing the accomplishments that research has done and how those are implemented into technology transfer and actually changes behaviors.

DR. GABRIEL: Thank you. Caroline.

MS. DeWAAL: Caroline Smith DeWaal, Center for Science in the Public Interest. I have lots of edits to this section, but I'll try to condense them into kind of the overriding theme.

We have a tremendous concern with the fact that risk be the requirements for cost benefit analysis and risk assessment appear to be delaying needed public health measures. And the best example of this right now is the outbreak from Sara Lee products produced by the Bil Mar Company, which last year sickened 100 people and killed 21 because of listeria monocytogenes in a ready to eat meat product.

To date, it has been nearly a year since that outbreak occurred. FSIS has taken no proposed regulatory measures. In fact, they are telling us that they can't do any new regulations to address this hazard, whether it be labeling or mandatory testing or anything else because they don't have the cost benefit data that would be required to satisfy the Office of Management and Budget, as well as their own office of risk assessment and cost benefit analysis at USDA.

This is ridiculous. Twenty-one people died last year, and USDA hands are tied by the requirements for risk assessment. The system is broken. And so in this document, and particularly the first paragraph, I would like to see some reference to the fact that science and risk assessments shouldn't stand in the way of needed public health measures. Clearly, science and risk assessment should inform the rulemaking process. And to the extent that that risk assessment isn't available at the time that regulations might be needed, then in fact the agency should proceed with rulemaking on a temporary basis while the science and risk assessment process can catch up with the public health need.

So I think that that message needs to be clear in this document. I am really concerned that this document puts such a heavy emphasis on science and risk assessment that you are not recognizing the other side of the equation, which is the fact that there are times that regulators should act to address urgent public health matters.

So I have lots of edits that go to the issue of timing, making sure risk assessments are done in a timely basis, making sure agencies don't wait for risk assessments to take needed actions. I would also -- I have some general questions. And I would like -- I like a lot of the format and the clarity. But I also think now we are getting to the point where we need to know who does what, what are the timelines, the funding, those kinds of questions. I mean, I like the document as it exists. But I think we are reaching those questions now.

On objective two, I think you really need to expand the objective itself to include information sharing, so it expands surveillance, data collection, and information

sharing because CDC, with all due respect to the wonderful scientists who work there, can be kind of a black hole for public health information. A lot of stuff goes in and it doesn't come out very quickly, or sometimes at all.

So we would like to see a separate action item saying that they should be publishing outbreak and other food safety surveillance information annually. That should be a separate action item.

And also, I want to just say, we really like the concept of objective four, identifying emerging and potentially high risk food safety threats. That would be great if the risk assessment process was ahead of the curve. Right now, though, we are really dealing with a situation where it is significantly behind the curve. But I like the fact that, you know, we are out there looking for emerging hazards.

I would suggest, just from a straight editing standpoint, that you change sensitive subpopulations to vulnerable populations throughout the document, just for consistency. And also, I really like the fact that you have action item one under objective five, enhancing communication and coordination of activities among the laboratories at local, state, and federal levels. The current coordination of state labs and the whole system of working with the labs is absurd. And we would like to see that improved. Thank you.

DR. GABRIEL: Thanks, Caroline. To my right. Dan.

MR. SOWARDS: Yeah, Dan Sowards, AFDO. AFDO, under the -- one of the objectives under goal one, science and risk assessment, within this goal, involves

establishment of national risk based standards to control food safety risks. AFDO believes that the terms "coordinated" and "unified" need to be added to the objective, and that this should be translated into a specific action item.

The one example that I think the states typically give on this is the methyl mercury in fish, that you have two federal agencies that have done different risk assessments, have basically a different standard there. And a lot of states I know are confused on which risk assessment module, which standard to use. So I think that the federal agencies need to coordinate this and unify this with respect to risk assessment.

DR. GABRIEL: Thank you. Anyone else on that side of the room -- side of the table? Ms. Donley.

MS. DONLEY: Nancy Donley, from STOP. I think Dr. Hirsch had made an interesting comment a little earlier that sometimes that there are two things going on with science, as it shows out -- it can show what is there, but it also can point out deficiencies in what isn't. And I think for that reason, we have to -- I am concerned as well on the total reliance of this document on science. And while I support the need for good science, there are times when it just doesn't exist. And we can't hold on and wait until the science catches up with the problem.

So I think somewhere in here I'd like there to be -- you know, make that identification that there are times when emergency measures must be taken and the science will follow.

DR. GABRIEL: Thank you. How about behind me? Oh, I'm sorry.

Dean.

DR. SIENKO: Dean Sienko, from Ingham County Health Department. A couple of comments on objectives one and two. And just to sort of broaden the scope in which we think about these things, in the final action item, objective one, to develop protocols on latest scientific information, I would like to encourage you to think about doing that in the, like, primary care health setting. My concern is that people may present themselves to emergency rooms or to their primary care physicians or other health care provider with a particular problem that would be indicative of some human health risk. And I'm concerned that the medical community really knows how to respond to that in the appropriate way.

I suspect that if you gave a clinical scenario, and you gave it to ten physicians and said what would you do, would you culture, wouldn't you culture, what would you culture for, would the lab be able to do that, you may get very different answers. And one of the ways that I think that we try to control for that is we offer some protocols, some clinical guidelines on how to deal with those particular situations. So I think that would be an area that would be helpful to us as we try to disseminate that information to our providers.

And objective two, using surveys and surveillance and other tools, I would certainly encourage you to do some surveys perhaps of behaviors. We talked about education, and then we also talked about having education translating into actual behavior. Well, do we know how the public, either consumers or people who work in the industry,

what their behaviors are?

We have a beautiful tool called the behavior risk factor survey that CDC uses. Have we ever asked the food safety question on that? I don't know that we ever have. And I think not only will that give us some information, but it also can be used as a stimulus to discussion on this issue because the press picks up on those kind of things. They talk about what the gap is or how good it is, how bad it is. I don't have any idea what it would be. But I think it would be something that we could look at behavior as well as trying to strengthen on the professional side the whole definition of surveillance.

I don't think most professional health care workers know what surveillance is or how surveillance fits, or what the reporting requirements are. And I think we need to strengthen that in order to get those numbers in to appreciate the magnitude of the problem as well as particular circumstances that may be presenting at a point in time.

DR. APPLEBAUM: Rhona Applebaum, NFPA. I would just like to echo and support what Dean just said as it relates to getting a handle through surveys in terms of what the behavioral practices are as they relate to food safety issues. There is a lot when you are looking at those types of surveys as it relates to risky behaviors or practices that are deemed unhealthful, be it the consumption or alcohol, tobacco, drugs, et cetera. And I think that is something that is long overdue because we don't have a good handle in terms of what those types of practices are and ways of developing, if you will, programs and educational curricula to, as Nancy mentioned earlier, to changes those types of behaviors.

So I want to support what Dean just said. We need to have better information in terms of what those risky behaviors are. And they are not just confined to, if you will, the drugs, the alcohol, tobacco, and other forms of what people deem unhealthful practices.

I also want to mention, and it is probably understood, but in the event that it is not, just to make -- just several points in terms of how -- you know, the listing of the objectives. And again, NFPA has not had an opportunity to review in depth all of the specifics of the plan. We will do that when we provide our comments. But just to make sure that when the plan is taken back and an action for an operating plan is developed, an operations plan is developed, that the objectives are not looked upon in isolation, to make sure that it is understood that there is a lot of interaction and a lot of cross breeding, for lack of a better term, as relates to these objectives.

Specifically, I was not shocked, but I was just wanting to make sure again because they are going to be going to different people. I don't know how this is going to be done, but perhaps there will be groups who will do objective one, objective two, objective 3, but to make sure that there is a holistic approach given to each of these goals and the objectives that make up these goals and obviously the action items under each of those objectives.

But it is objective four which I think is critical, the identifying and emerging of the high risk food safety threats. And then I looked at objective six as it relates to surveillance. Again, it is probably understood, and I am just giving me word of a caution

to ensure that these objectives are not looked at in isolation because you are not going to be able identify those emerging and potential food safety threats if you are not employing those tools that you need in order to make our collective jobs as effective as possible.

DR. GABRIEL: Thank you very much. How about behind me?

MR. MANN: Jim Mann, Health Minder. I just wanted to reiterate some things that Dean and Rhona just said about the science and applied science. When I think about this, so many times we are defining science and microbiology and epidemiology in the mathematics, you know, to be sure it is included in here as part of the sciences for its predictive values. We are studying these patterns, we are seeing these things. And there is a tremendous predictive value in these things that we don't have to wait for someone to die before we can do something about it.

So I would encourage to think of the science and science based as a very broad stroke on science, and the other on the applied side, the psychology, as soft as that may be in a lot of these applications, until our knowledge is implemented, as it says somewhere in here that I read. And that is so very true, that the limiting factor out there is what gets out there to the end of the train. So the psychology of what works, what doesn't work, to be realistic about that.

When we think about the food safety professionals and how much we all can do in this room, who do you suppose is the largest group of food safety professionals today? They are the food handlers out there handling the food. They are the people that need to know. They are the people that need to take some responsibility and assure there

is 3-, 400 percent turnover as a lot of our food processing is moved to the retail level. It is a pretty scary thought. But there is a lot of work that has to be done there. And think of that, please, as we are rewording these pieces. Thank you.

DR. GABRIEL: Thank you very much. Anybody else in the back on the left here? If not, how about at the table?

MS. BILLAUER: Barbara Billauer, Association of Environmental Health Academic Programs. We are talking about what is good science, sound science. But how do we know? The obvious answer is that the scientists will tell us. But oversees the scientists? And on a personal level, what I would like to see happen is, in the future perhaps, that we take pains and perhaps the agencies take pains to make available introductory educational classes to train the public to understand what goes on in risk assessment because at the bottom line, the EPA risk assessment is not a scientific method. It is really a default method when there isn't enough science. And that is good because we need to be able to deal with when there isn't enough science.

But on the other hand, the public needs to understand, not to absolve the federal government, but to make sure that the governments are doing what they are supposed to do as to what goes into a risk assessment, just what are the steps to make sure that they are all carried out and to make sure that one side or another side of stakeholders is not inappropriately exercising a louder voice. To paraphrase a statement, an educated consumer is our best citizen, to make sure that everybody is doing what they are supposed to be doing.

But then we talk about the future and identifying emerging threats and bioterrorism and emergencies. And that goes to the future of science. And the question becomes how do we train the future scientists to do good science, and will training future scientists to do good science be the same as training the scientists today. And what seems to be happening is that as we know more, all the fields seem to come together.

We talked about what is more important, surveillance or research, hard research. And in the spirit of conciliance, really surveillance and research do go hand to hand. And I'm not sure in the future, recognizing a prodromal threat or something that has happened that hasn't done real harm -- and we are having problems recognizing -- something that has done been harm -- can be done without an understanding of epidemiology and biostatistics and toxicology and vector control animal transition and microtransmission and microbiology.

Now, obviously, someone can't be an expert in all. But the scientist of the future, or at least the public health scientist of the future, is going to need to have a much more multidisciplinary background than the previous types of scientists that we might have relied on in the past.

Now today, things may be going on in an ad hoc basis because the scientists are so well connected, and they transform or transmit information on an informal basis. But in the future, we are going to need to make sure that the training of our future scientists in this field of environmental and food health is an integrated, well coordinated curriculum where the students are made aware of, well, maybe we should alert the

laboratories that they should be putting in a culture for something that is not on the standard list.

Who is going to tell the laboratories that? And if we wait for a federal agency, it might be too late when a local food health person might have observed something. And so I think we need to focus on the training of the future. In terms of performance objectives and measurements, we need to have boards of oversight on the educational process, on the environmental health curriculum to make sure that the future students who are going to go into food handling or inspection or industry have the appropriate training.

We are going to need to establish criteria for licensing or certification, and we are going to need to integrate the fields of surveillance and research so we don't have both sides saying mine is more important when each side gives clues to the other, and we are all better off when we integrate knowledge. Thank you.

DR. GABRIEL: Thank you very much. Next?

MR. EMERLING: My name is Stan Emerling, and I represent the North American Meat Processors Association. I'll want to have some other words further on when we get into risk management. But what -- and there is much that has been said here on this issue that I can totally agree with. We are very sensitive to the concerns because without addressing those, our whole industry can be at risk. And so it is very important that we do. But Caroline and both Nancy have raised some things that I just would like to throw out on the table for you to think about.

When the ask for temporary regulation or emergency rules -- and I can understand they need to look at that, and perhaps they need to be looked at, you know, like with an instant response team if we don't have the science right at that point so that we can come up without trying to make a scientific or nonscientific analysis, but something that can address that issue at the point in time that it is needed. Otherwise, if we have regulation, you know, I know we have been trying to get rid of some regulations for years and years that we know are erroneous. But you can't do it for a number of different reasons, Delaney being an example.

The contradictory opinions we are now having on what we should eat or what we shouldn't eat, although it may not be regulations, they get transferred into food codes and things of that sort. So I think we ought to be very careful about what we do when we say we do things without science, but we do need an immediate response type vehicle to address those questions.

DR. GABRIEL: Thank you. Others on this side? Towards the end there.

MS. KELLY: My name is Karlease Kelly, and I represent the Food Safety and Inspection Service Technical Service Center in Omaha, Nebraska. And I have a few comments today related to objective five, particularly in regard to action items two and three.

Just as a point of background, the Technical Service Center answers questions and provides technical guidance and assistance on a daily basis to hundreds of folks in the production who are involved in the production of meat, poultry, and egg

products. We also interact and provide information to government officials who are making decisions about inspection and enforcement. And so that is the perspective that I am bringing with regard to these comments.

With regard to objective five, action item two, it talks about developing programs to encourage scientists from academic institutions to participate in governmental food safety and public health activities. And I think that we all would agree that this is something that is very useful, something that would be helpful to achieve.

When I read the action item, my overall impression, however, is that the emphasis is on having scientists and folks from academic institutions participate in research areas or in policy development activities, which is helpful. I would encourage you to add to this action item the idea that it would be helpful to have these people also participate in applied efforts such as the one that we are providing at the technical service center so that they can become involved in discussions related to implementing some of the policies that have been put in place.

I think this would be a very rich exchange for people who are involved in answering questions. I know at the technical service center we would benefit from having folks who are maybe, say, recently involved in some academic programs. And I think it would also be useful for the scientists to see things from that very applied side. And it might actually focus some of the research efforts in the future on some of the emerging issues that we hear about on a regular basis.

With regard to action item three, it talks about establishing extramural

programs, for example, centers of excellence, to conduct targeted research and develop training programs linked to food safety and public health. I guess I would like to encourage consideration of adding the word, following the word "establish," the word "and/or identify."

I think we have had several comments this morning about the fact that we do have a wealth of resources that exist already at the local, the state, and the national or federal level. We believe that the technical service center is one of those such resources that perhaps might be identified as a center of excellence. We don't feel that it is necessary always to create something new, but maybe to build, as people are talking about, on a foundation of something that is already out there and working effectively. So perhaps that could be added. Thank you.

DR. GABRIEL: Thanks very much. Anyone else on this side? How about in the seats in the back then? I think we have one taker.

MR. PARK: I am Doug Park, with epidemiology in the Michigan Department of Agriculture. I would like to draw attention to the Federal Register notice and line three of that Federal Register says, "The purpose of the strategic plan is to reduce acute and chronic food borne and water borne illness by further enhancing the safety of the nation's food supply."

But when you get into the first goal, in looking at, I suppose, objective three, the reference to water borne disease is somewhat -- perhaps there is a tacit reference there. But if you look at the first action item under objective three, there is not a

reference to water borne disease. Those of us in state agencies who are charged with the investigation of reported water borne outbreaks are the same individuals who are charged with the investigation of food borne outbreaks.

In fact, the principles of methods used are the same. The agencies and states and local agencies responsible for the construction, the isolation, or the sampling of those supplies are using principles that are really delegated through them by the EPA. But in terms of the water borne disease investigation principles, those are really delegated to public health agencies and epidemiologists.

So the question I would have is should we have more specificity in this objective in perhaps the first action item regarding water borne disease.

DR. GABRIEL: Thank you very much. Nancy.

MS. DONLEY: I'm sorry. Are you coming around again?

DR. GABRIEL: Yes, I am coming around again. Everybody has a chance.

MS. DONLEY: Nancy Donley, with STOP. I just want to make an observation and then ask the task force a question. The observation is that I think it is critical that when scientific studies are done, that it is very clear who has done the studies and very clear -- I guess it is just who has done the studies, and we can make the determinations of bias or unbias on the part of -- I guess of the public. So -- because, frankly, there is just some science that is going to be viewed a little bit more skeptically than other sciences, depending on what your perspective is.

So that is an observation. So I would like to see that that all scientific

studies get very clearly documented and where they originate from.

And second of all, this is the question to the task force, is what is your definition, or what did you have in mind, with sound science? Can you define that?

DR. GABRIEL: Well, I can take a crack at it. I don't think we spent a lot of time, you know, coming up with a unified definition of what we mean by sound. But, you know, clearly we are talking about, you know, science that is peer reviewed. We are talking science that withstands sort of the test of time in terms of reproducibility. I mean, to me, those would be the two primary elements that I would look to to determine whether or not we are dealing with a credible body of scientific evidence. I don't know if others want to comment on that.

DR. WOTEKI: I think that is a good summing up of the task force's sense of what the term sound science means.

DR. GABRIEL: Okay. How about in the back, to the right here? Anyone else at the table? Oh, I'm sorry.

MR. HOLMES: That's okay.

DR. GABRIEL: Speak up.

MR. HOLMES: I will, as soon as the microphone comes on. My name is Scott Holmes, and I am chief, environmental health division, with Lincoln Lancaster County Health Department. I am going to take off all of my other hats and just speak as public health professional regarding two issues related to risk assessment.

The first is that I think there should be an action step to develop an

epidemiological research agenda related to food safety. And what I mean by that is if you look at some of our larger issues in our nation such as heart disease or cancer, things like that, the studies that have been done have not been -- that have had an impact in the public side of things have typically not been the basic research. It has been things like the Framingham heart study, the ten cities studies, where they have identified what are the major risk factors here for developing disease.

And I think that could be very useful in the area of food because, first of all, it has not been done. And CDC has taken a few stabs at it right now. But I think that is a critical area to look at. That would be a very big issue, and it would take a much different group to probably look at that.

Secondly, this comment is going to come around a bit. But first of all, APHA, American Public Health Association, in 1990 published a paper that was entitled something like this -- I can't recall exactly, but it was called, "Making Public Health Policy Decisions in the Absence of Scientific Data." It is about a 10 or 12 page document. It provides an excellent framework for doing exactly what has been advocated, and that is making decisions when you don't have all of the numbers. And despite the fear -- and I appreciate that concern on the part of industry -- that is something that is done all the time and has to be done.

And this is sort of a backwards negative comment toward our friend Caroline here. That's one of the things that local and state health departments do much better than the federal government, and that is be responsive to need. If you look and

identify where was the first higher temperature adopted for e. coli for cooking hamburgers, it was not by USDA or FDA. It was by the state of Washington, Seattle King County Health Department. Why? Because they had an outbreak of e. coli.

Did they have all of the risk assessment to tell you exactly how to cook hamburger to kill e. coli? No. But they had some pretty good information, and from that made a very sound public health decision. It wasn't a sound scientific decision perhaps by many judgments, but it was a very sound public health decision, policy decision.

And so I just encourage us to consider those concepts. And I assume there have been other papers written since 1990 on the same subject. I just don't have the familiarity with them, and I'll just pass on that.

DR. GABRIEL: Thank you very much. Cathy, did you want --

DR. WOTEKI: Yeah. I actually wanted to go back to the point that Nancy Donley raised a few minutes ago and ask some more questions, particularly as it relates to objective one and the action item that is the third of the action items there.

Nancy raised questions about reliability of information that comes from the private sector as opposed to publicly funded research activities, I guess is one way of characterizing what your concern was, Nancy. And within the task force, we have had on this particular action item some discussion back and forth about whether articulating an action item, as we have stated it here, that develop protocols to ensure that the latest scientific information is used consistently in development of risk assessments, whether the wording of that objective is setting a bar that is by far too high, and also that it might be

also an impediment to moving us forward in decision making activities.

There has also been comments that have occurred in our internal discussions about whether the fact that in many cases in our risk assessments industry is the best source of information. They probably are in possession of more information, scientific information, than the regulatory agencies or the scientific community might be about the effectiveness, for example, of certain interventions, or the presence of pathogens or other substances of concern from a food safety perspective in the products that are perhaps the subject of the risk assessment.

So what I wanted to do is to go back to the point that you raised because I think it is a very important one that we need to consider in a discussion of basing our food decision making process on science. And when the sources of information are going to be in the private sector, how can those sources of information be tapped in order to improve the risk assessment process.

Now I might hasten to say that in most cases that I am familiar with, the industry has been very forthcoming in providing information. But I know that there are some concerns raised by some that perhaps some information is not coming forward to those who are conducting the risk assessments.

So that is one issue that I wanted to see if we could elicit some further discussion about.

MR. HODGES: Jim Hodges, American Meat Institute. The title of the section that we are discussing talks about science and risk assessment. And to move away

from that is clearly a mistake because we enter into opinions and perception rather than focusing on the science.

Your specific question deals with the credibility of the research or data that comes from the private sector. Clearly, there is a wealth of data out there. The American Meat Institute Foundation funds several million dollars worth of research each year in a variety of different areas, some of it related to assessments and surveillance of food borne pathogens throughout our food system, and to discount that kind of information as being noncredible just because it is generated by an industry that wants to improve food safety I think is clearly not in the best interests of the consuming public or enlightened public policy making.

It would certainly seem to me that we need to have the best available data we have, and we would support the definition that has been put forth here that it is peer reviewed, published, and stands the test of time. That's -- it is not the source that is the issue of credibility. It is whether or not it has credibility in the scientific community and continues to have that.

So I would clearly urge the panel and the report -- I think in a number of areas -- and I was going to make this comment earlier, but I was going to talk about it more in the risk management area. Sprinkled through there are the issues of cooperation, private sector. But it does not emphasize it very heavily at all. And I would certainly think that there is an opportunity in this document to look at what is available in the private sector and how we can better integrate that with the public policy issues. I'll say

public policy in the broad context. And we have clearly participated in that arena in the past, and we will continue to do that in the future.

DR. GABRIEL: Nancy.

MS. DONLEY: Thank you. Nancy Donley, from STOP. This is a tough, tough, tough problem that has to be wrestled with. And I think there probably is some very good scientific information that has been done by industry, and it could probably prove to be very, very helpful. Also of concern, though, is -- and I don't know how to control this. I'm just going to throw it out on the table. How it would be controlled is what science has been done that we don't know about?

So you have got that flip side as well. And, you know, there could be something that would be very beneficial that way as well. So it just complicates the matter even further.

DR. GABRIEL: Over here, and then to Joe.

MS. BILLAUER: I am going to jump in and use the risk communication portion to address the comments that Ms. Donley and my colleagues here on the left were talking.

MS. WAYLAND: Identify yourself, please.

MS. BILLAUER: Barbara Billauer, Association of Environmental Health Academic Program. We talk about credibility on these reports. And I'm not sure that is the right word, credibility. Somehow the legal community stuck in credibility. I don't see the word credibility used in the scientific community, the words reliability or

reproducibility.

I think we need to look at whether the reports are biased. And I mean biased in the scientific standpoint as well as a common language. The reports where the data can be -- the data can be accurate, and the analysis can be biased, or vice versa. If there is a systematic bias because someone comes in with a preexisting belief that can't be separated out, then I think the public needs to know that, and certainly the oversight committee needs to know that. If there is not, the public needs to know that, too.

But giving the public the skills -- and this is why I strongly advocate consumer education to sort out biases so that we don't make knee jerk decisions, well, this is a good credible study because it comes from a publicly funded institution, and this is a bad study because it comes from some private institute. That is full of bias in and of itself. And I think that is why we need to learn the skills as consumers to be able to separate out good data from bad data and good analyses from bad analyses.

DR. GABRIEL: Thank you. Joe?

MR. LEVITT: Thank you. I just wanted to see if I could focus a few more comments on some of the points that have come up, particularly with what in some sense feels like a little bit of a cross current. And I want to probe to see if it really is, or if we are talking two related points. The first, of course, is the general desire to have a strong scientific foundation beneath what we do, for example, our HACCP programs and so forth. I think everybody agrees, and the group feels good about that. But that gets juxtaposed against the point that was made in the back, I worte it down to be sure I got it

right, making sound public health decisions in the absence of full information.

That is one of the points Nancy was getting to, Caroline was getting to. And I guess what I would like to probe is I'm not sure those two are inconsistent. They are presented as if they are inconsistent. But I'd like to see just see if we get a little more discussion around, you know, does the quest for science prevent us from making important decisions before all of the data that we would like to have are in.

DR. GABRIEL: Caroline.

MS. DeWAAL: Thank you. Caroline Smith DeWaal, with the Center for Science in the Public Interest. We are seeing a trend, and it is a trend both in our law and also as you look internationally at Codex, that regulators are being told they cannot make decisions until they have a risk assessment. And there are specific -- there are legal requirements, actually, over at USDA now on this.

The problem is that that is getting in the way of needed public health decisions. I thought the point made from the gentleman from NACCHO was quite good in the sense that I have been at meetings of the National Advisory Committee on Meat and Poultry Inspection where the state public health people say, I can't believe you can't take action more quickly. We could never do that in New York state, where we are dealing with, you know, numerous public health problems. We have to make decisions much more quickly.

The reality is at the federal level, your hands are becoming tied by these laws. I would like this document, the -- it is not inconsistent with the scientific basis and

needing that foundation. It is just this document should reflect what the states know and what the public health community knows, that there will be times when you have to make decisions when the science isn't in.

DR. GABRIEL: Dan.

MR. SOWARDS: One of the concerns that the Association of Food and Drug Officials has had over the last four or five years with some proposed national preemption legislation has been the ability of state and locals to react in a timely fashion to public health emergency situations because certain language that exists in the proposed bill would preempt the states totally on these types of issues because the reaction would have to be based upon what the national standard is, as opposed to what may be emerging out there.

So again, the state and the locals need that ability, as does the federal government, to be able to react to emergency and emerging public health situations without having their hands tied by specific legal requirements. And one of the questions I know that has been posed is what statutory changes might be needed. AFDO will in our comments advocate three or four major changes. And this would certainly be one of them.

DR. GABRIEL: And one of the questions that we asked leading into this discussion was -- getting to that, sort of what are some of the possible changes in statute that might be required to help implement this goal, another focused on the potential organizational issues that we might want to address to make sure we can tackle these

goals as effectively as possible. Really, that hasn't been addressed by the comments that we have heard so far. Does anyone have any information or comments on those two elements, both the organizational aspects as well as the legal?

MS. SOSA: Meryl Sosa, for Food Animal Concerns Trust. We are very concerned about the need for statutory change. And our perception is that really there needs to be a complete overhaul of the statutory system because it is just not effective. And, for example, we have a system where there are 120 inspectors inspecting pasteurized egg product plants. And there is only one person who is responsible for in-shell eggs. That just doesn't make any sense because all of our -- I mean, the majority of our problems that arise from eggs are going to come from in-shell eggs which have not been either -- there are a variety of problems that they could have.

But without proper statutes apportioning inspectors to right places and proper statutes giving enforcement mechanisms and things like that, we are just not going to make any progress. And we don't need a risk assessment to tell us that pasteurized egg products are safer than in-shell eggs. We know that. So we don't need to do that.

So in some areas, I don't see why we need a risk assessment to tell us to change the statutory structure. We just need to go ahead and do it. And so I think what our big problem is we recognize the need to have a strategic plan. But part of this plan has to be an analysis and an overhaul of the statutory structure so that the statutes do make sense.

For example, we're a producer of eggs. And our -- we really don't know

who is responsible for food safety, who is responsible for grading, who is responsible for all of these different things. I mean, it is really hard to tell, according to the statutory structure. And in fact, because of the fragmented nature of it, not all of egg safety has been addressed, and now we are going through this process to make sure that it is addressed. But it has been a really time consuming process to get to the point where we are going to have an egg safety plant. And I'm not sure when that will be exactly. But it is making progress, and we are pleased about that.

But I think egg safety is really a good example of where we need an overhaul of the structure and where we need to not necessarily wait for food safety -- for risk assessments because we know certain things. And I think the National Academy of Science brought this to the attention with the continuous inspection requirement. And we have to be open to these changes. And that is why I think a single food safety agency would be good because it would force this whole overhaul. And I think that is really necessary.

DR. GABRIEL: Thanks. I guess I was looking at organizational and legal comments based on this goal. I mean, certainly, we could have, I think, a broader discussion about the overall situation. But any specific ideas about how we might do things differently to more effectively implement this goal and the objectives would be very helpful.

MR. WHITNEY: Jim Whitney, president of the Whitney Group. My company is a consulting practice to food service equipment manufacturers. Coming from

the world of manufacturing as well as the food service industry, one of the things I look at is when you are dealing with regulation, surveillance, you are dealing with minimum requirements, and you are dealing in a reactive environment, you will always be in a situation where you are trying to adhere to minimum acceptable standards.

I would encourage the task force, the committee, to think outside the box a little bit. Look at the world of manufacturing. We have any number of regulations that mandate minimum acceptable practice. Parallel to that, we have a federal program, the Baldrige Quality Award (phonetic) that says here is the best practice, here is world class, here is what goes beyond the minimum required standards that has been proven to be effective, not necessarily with sound science.

What is the difference, to use Ms. Donley's example about house foundation earlier, I can build a house that meets a minimum acceptable building standard. When a crisis occurs, when the hurricane hits, the minimum acceptable house is going to collapse. I can establish and promulgate best practices, which are not mandated, but which are sound, which are documented, which are widely promulgated that establish practices that go beyond the minimum but have been proven to be effective. I would consider this committee to consider that type of parallel track to get beyond simply surveillance and mandated compliance and to establish documents and publish best practices.

DR. GABRIEL: Thank you very much. Any more -- here we go.

MS. ZAWEL: Thanks, Cliff. Stacey Zawel, with GMA. I wanted to -- I

don't have any specific guidance to add. But I wanted to react to some of the comments that have been made with respect to science and risk assessment, and would in short part oppose some of the comments in that I think that the government has moved in a very positive direction to assure that science and risk assessment are the basis of government regulation.

In addition, it certainly helps us to take a posture in an international standard setting environments as well. And I would really hate to see the United States food regulation system cascade down to that of some of our international counterparts that don't place science and risk assessment at the very top. And what I mean is if we don't have that, then perhaps we would take the precautionary principle and we go full bore ahead that way, which I think would be tragic.

On the other hand, we would not advocate necessarily waiting for all of the science to come in. I think that we recognize that we have to make decisions based on the best science available, as Bob Buchanan has told many people over and over. And I think that that is the key.

DR. GABRIEL: Thank you very much. Caroline?

MS. DeWAAL: Just on the very specific question you asked.

DR. GABRIEL: Thank you, Caroline.

MS. DeWAAL: I think at a minimum, we need to look at the mandates on cost benefit analysis at USDA. They appear to be duplicative of jobs which are already being done by OMB. There is also -- I don't know the statutory authority that gives OMB

the power it has to require such heavy risk assessment and cost benefit analysis to accompany every rule. And it is not -- I mean, we support those. And in a perfect world, they should be required for every regulation. But we're dealing with emergency food safety situations.

We are also dealing with hazards, as Meryl points out, that we know are out there. We know that listeria is in ready-to-eat meat products. We know that salmonella enteritis is in eggs. But the public doesn't know. And we need to take steps as the government to change the systems without waiting for a crisis.

DR. GABRIEL: Thank you.

MR. OSAKI: Carl Osaki, formerly with Seattle King County Health Department. I would like to just share with you an experience that resulted from the Jack-in-the-Box outbreaks in '93. Cooking temperatures -- we had to respond immediately to dealing with that particular issue of undercooked hamburgers. We set a cooking temperature of 155 degrees Fahrenheit based upon available information that we had. Much of it was science based information that we were able to get at that point in time.

We set that as the standard. We set that into rulemaking, and we actually passed a regulation in the state of Washington to set that standard. It is still 155 degrees Fahrenheit. However, subsequent to our involvement, USDA, and I believe FDA, came out with the standard of 160 degrees. Believe me, it confused our community. The media began to ask questions, why is your standard much less than USDA's and so on.

Well, let me give you a practical situation. If you cook a frozen

hamburger, it will not cook at the same temperature equally on that particular hamburger. As a matter of fact, there are portions of it that will cook at 155 degrees, whereas another part might be 185 degrees. If you set the minimum temperature of a hamburger, cook it on the grill at 155 degrees, it is much different than cooking the hamburger at 160 degrees minimum requirement because you are going to end up with a hockey puck by the time you get done with that hamburger. So there are a lot of other issues going on besides just scientifically based information.

There are also times when we at Seattle King knew that we were getting into an outbreak situation that was not a bona fide outbreak. However, we did it as an outbreak because we felt it was an opportunity to communicate to the public and to share information about what it takes to deal with a particular situation. So we saw that as an opportunity. It had nothing to do with science. But it had everything to do with communicating effective information to the public in a real common sense, understandable language.

DR. GABRIEL: Thank you.

MS. DeWAAL: Can I just amend my remarks also to say the agencies need to have emergency rulemaking authority explicit? They either need to have it enacted or they need to be empowered with the current statutes. But they need emergency rulemaking authority.

DR. GABRIEL: Okay. I guess I'll take this as sort of the last call. Does anyone have any additional comments they want to make on this goal? Then I'll turn it

back to Cathy.

DR. WOTEKI: As we head into lunch, let me just say -- oh, I'm sorry. One final comment.

MR. MARTINEAU: I'm Damian Martineau, representing the American Culinary Federation, a professional organization of chefs and cooks. And as the gentleman just pointed out, there are a couple of things that come into play here. And I'm learning as we go as well. I know science plays an important role in food safety, as a certified executive chef. And I also know that there is a practical and an operational procedure that needs to take place in our approach to food safety.

Now he just pointed out, with good clarity, that a hamburger is going to be different temperatures at all different points of the hamburger. Another point that -- you know, if you look at the temperature analysis, how do you take the temperature of a hamburger? You know, there is a lot of devices out there, but if I am serving a banquet for 5,000 people, how am I going to take the temperature of all 5,000 hamburgers? It would take me three hours to do that.

So I think science is important. But we have to have an element of practicality and look at the operational application of the science that you develop. Thanks.

DR. WOTEKI: Right. Thank you. I'm sure everybody is going to rush out and order hamburgers for lunch.

(Laughter)

DR. WOTEKI: Just for clarity, though, this whole issue is one that I'm glad was raised because it is very important, as we particularly consider the risk communication goal. Certainly, we want the information that is communicated to professionals as well as to the public to be information that they can incorporate into their daily lives, their jobs as well as at home. And this is an area that although one would think cooking a hamburger is a fairly easy, straightforward thing to do, the discussion that we have had so far also illustrates there are some problems associated with it.

And just to clear up any confusion, the guidance to the commercial world is to cook hamburgers to 155 degrees for 15 seconds. And that will kill 0157:H7. The guidance that is provided to the public, because it was sensed that that message would be a little bit hard to incorporate into daily food preparation at home, is cook to 160 degrees and use a thermometer.

There is also evidence that has come from the research laboratories that shows that you can't rely on the color of hamburger any more as an indicator of the temperature, the doneness. So that is why it is difficult to give a general advice about the color of the final product because the hamburger can be brown at 160 degrees all the way through, or it may still be pink in the center at 160 degrees.

So this is just, I guess, an introduction to the afternoon's discussion. We'll reconvene at 1:45, I believe it says on our agenda. We'll see you then.

(Whereupon, at 12:37 p.m., a luncheon recess was taken.)

//

//

//

//

//

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(1:48 p.m.)

DR. WOTEKI: For the sake of getting us out on time this afternoon, I think we should begin to get seated so we can get started.

(Pause)

DR. WOTEKI: For those of you who maybe just be joining us after lunch, please feel free to take a seat at the table here if you are planning on making some comments and actively participating in the discussion. If you are not planning to, you might take a seat towards -- in one of the other areas, either along the side or along the edge of the room. And since it looks like we have got several open places or more around the table then we did this morning, don't be bashful, move up. And we certainly want to hear your comments.

We would like to turn now this afternoon to the second goal that has to do with risk management. And we would like to address the same four questions that were addressed this morning. And leading the discussion for this section of the agenda will be Joe Levitt, who is the director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration. Joe.

MR. LEVITT: Thank you again. Welcome, everybody, back from lunch. We'll use the same general format that we have used this morning, starting at the tables. To warn people going back and forth, I guess we'll start at this side, although we may need a few more people for this side in order to do that.

This is the largest section of the strategic plan just by number of lines, if you count it that way, so that there is a lot in here. If we could ask people, you know, again to focus, as you have been. One additional item that I would point out and try to draw out of the discussion, and that is to be sure that we are thinking of the full range of potential food safety hazards. A lot of the focus has either been very general, which is good because it seemingly applies to everything. But most of the specific discussions are on pathogens. And that is correctly so because they are such a big issue.

But in developing the strategic plan, we very much wanted to broaden the scope to a wider range of food safety hazards, including chemical hazards, pesticides, and others, and so forth. And so as you go through, please be sure you are keeping the full range of hazards in mind as you bring forward your issues and make your comments.

With that, who along this end of the continuum would like to open the discussion on risk management? Well, okay, all the way on the right side to the back, please.

MS. LAUTNER: Beth Lautner, National Pork Producers Council. I just had a couple of specific comments and additions for clarifications. Under objective three, under action items, when you are listing different possibilities for surveys or data collection, I wonder if that section under monitor hazards and prevention practices had some clarifications to it.

One that I would point out, just from representing an animal producer group, would be specifically to have the words in there building or enhancing current

national animal surveys. There are current systems in place, such as NAMSIN (phonetic). There are opportunities in a very cost effective way to tie on additional projects onto those surveys.

There is some plans to turn those into sentinel programs rather than five year surveys, into sentinel ongoing monitoring programs. And I think if there could be a phrase in there on building on current national animal surveys, it would be useful.

Then on the fifth action item, under objective three, I just wasn't clear when I read that, the one that talks about developing a network of animal diagnostic laboratories, the systematic monitoring, and then it goes into -- in animal feeds and feedstuffs. I wondered if a couple of things had been collapsed into that one because that wasn't clear to me what exactly was being discussed.

I definitely see from the animal diagnostic lab side a value to having that as a sentinel network and coordinating what is being submitted and the results from animal diagnostic laboratories as a sentinel network for emerging potential public health organisms or changes in known organisms that are being tracked. There is a real value in having a network of the diagnostic labs to gather that information.

I'm not sure -- and they do have information on feeds and feedstuffs, but that is not their only function with the animal diagnostic labs. So perhaps if that could be clarified, what the thinking was there.

MR. LEVITT: Okay. Thank you. Yes, over here.

MR. SAUNDERS: Doug Saunders. I'm with the Virginia Department of

Agriculture and Consumer Services in the Office of Dairy and Foods. And I am also with the Association of Food and Drug Officials.

Under -- just a couple of things I wanted to point out. Under objective two, the second action item -- and this goes along with something that Dan Sowards mentioned earlier, where it talks about maintaining performance standard based HACCP programs and expand the use of this concept where appropriate, I think that perhaps it might be good to expand upon that somewhat and to add a statement, something to the effect of to include at least the hazard analysis, just to make that statement more appropriate and to get people to understand that with respect to risk assessment, risk management, that, you know, the hazard analysis is the starting point for all that.

Also, with respect to --

MR. LEVITT: Excuse me. Just to kind of clarify or reinforce those, Dan Sowards, I think, made the same point this morning in what he called a universal HACCP.

MR. SAUNDERS: Yes.

MR. LEVITT: Which some people think would mean a full blown HACCP program every year. That is not what you are advocating. You are advocating a universal initial step of a hazard analysis.

MR. SAUNDERS: That's correct.

MR. LEVITT: And then let that dictate what goes further.

MR. SAUNDERS: Yes.

MR. LEVITT: Okay.

MR. SAUNDERS: Also, with respect to allocation of resources, under the verbiage under the risk management, it talks about allocating resources where risk is high. If you go to the fifth objective, the third action item under the fifth objective talks about allocating enforcement resources on the basis of greatest risk. I would just like to add that I think that that is a key component to this particular objective and this particular goal. And it is also a barrier that I don't know how we overcome because there are a lot of instances already where allocating resources in a better fashion could achieve what we are trying to achieve much easier. And because of legal constraints and things of that sort, we are unable to do that.

So in addition to being an action item, I think that is a pretty tremendous barrier that somehow we need to find some way to overcome.

MR. LEVITT: Okay. Thank you. Yeah, Dan.

MR. SOWARDS: Joe, to add to what my colleague has said, in viewing what occurs, what actually occurs out in doing inspections, you have, whether it is a USDA plant that also does nonamenable products, or whether you have a state inspected meat plant that has a retail component, it seems silly to have to send -- you have a plant that already has an onsite inspector for the state meat program. But that state meat program individual cannot inspect the retail portion. He can, but if he does, that state program will lose that amount of funding, matching FSIS funding, for having spent that time doing the retail, which is nonamenable, unless there happens to be amenable product sold there.

So what you have is a budgetary problem from a federal standpoint that flies directly in the face of what we are trying to do in not only strengthening but eliminating duplication and filling in gaps. And so that is an issue, I think, that needs to eventually be taken up by the president with Congress.

MR. LEVITT: Okay. Thank you. Any other comments along this row? Okay. We'll again try to continue around. Any comments along back -- yes, please.

DR. GIBSON: I'm Dr. Jerry Gibson. I'm chief of the Bureau of Disease Control for the South Carolina Department of Health and Environment. And I'm also a member of the Council of State and Territorial Epidemiologists. And part of my job is to assure that our county and city health departments have the trained staff to identify and investigate cases and outbreaks of food caused disease, and to trace back the contaminated food and take preventive action.

These activities, as we have heard before this morning, so I'm not going to belabor it -- these activities of disease surveillance and outbreak investigation and a lot of trace back happen at the local and at the state level primarily, and therewith the safety net to catch where prevention fails.

In South Carolina, we find several dozen outbreaks involving hundreds or over a thousand people each year. And that is just a very small proportion of all the food borne illnesses that really happen. And I'm very concerned because in our -- and I think in many other city and county jurisdictions, there are simply not enough trained, dedicated public health staff to do the disease surveillance and the prompt, timely outbreak

investigations and the local trace backs well and fast enough to offer adequate protection.

And we all remember the Institute of Medicine report about public health of ten years ago or more. Well, the disarray is not all fixed, especially at the state -- and especially the county and city level, I think. In many areas of the United States, I believe that many local jurisdictions have no trained person to do this work and no dedicated trained person. And I suggest that the plans to build capability and reorganize our agencies really are not going to succeed unless we can assure the capacity at the level of our cities and counties to do this work of effective surveillance and rapid follow-up of the identified events.

And I would suggest that the objective and the action steps dealing with these areas of surveillance and outbreak investigation needs some special emphasis and some real support. I guess I am talking primarily about action step two under objective three of this risk management section. And I probably don't have to read it. It says upgrade the ability at all levels to conduct public health surveillance. I would add investigation and follow-up, something like that, in a timely and efficient way.

I would suggest that should be raised to an objective level rather than an action step. Thank you.

MR. LEVITT: Thank you. Just picking up on the last point, we heard a number of comments this morning about the surveillance and/or outbreak response elements here not having as much prominence as they have had earlier. If you have specific ideas on how to achieve that, please include that as we kind of go around. Okay.

Thank you. Other -- yes, please.

MS. DUNHAM: Thank you. Bernadette Dunham, with the American Veterinary Medical Association. We will be submitting written comments. But just to highlight a few on this one section, under your objective No. 3, No. 5, we certainly do have the same concurrence that Dr. Beth Lautner just mentioned a minute ago on this issue of having the diagnostic labs have the infrastructure necessary to have appropriate standardization for diagnostics and the communication that is going to be needed between all the various labs so you do have coherence. And that is going to be very crucial if you do want to have a rapid response that you just alluded to.

We would also hope that this particular action item does include the fact that we would be wanting to monitor zoonotic diseases in animals and the antimicrobial resistance of human and animal pathogens.

Under risk assessment, or management goal objective five, your last action item that recommends some of the critical points in the farm to table chain that we targeted for compliance inspections, we would hope that one part of the definition for most critical would also include the concept of most effective.

MR. LEVITT: I'm sorry. Most --

MS. DUNHAM: Effective. And then when you go to objective No. 7, this action item here was to expedite review of new animal drugs and intended to reduce food safety risks. This could also include your probiotics and new animamicrobials that would be necessary as well. And again, one more time, we are very, very pleased to see the

focus going far more to the science and risk assessment approach that you have now taken. Thank you very much.

MR. LEVITT: Okay. Thank you. Additional comments along this row? Yes, please.

MS. FINELLI: This is in reference to objective one.

DR. WOTEKI: Could you identify yourself please?

MS. FINELLI: Oh, yes, Mary Finelli. Identify areas where risk management gaps exist in the current food safety system.

MR. LEVITT: I'm sorry. And you are with what organization?

MS. FINELLI: I'm just a concerned citizen.

MR. LEVITT: Okay.

MS. FINELLI: Okay. I would like to -- well, problematic production practices are an area where risk management gaps exist, both in the current food safety system and in the strategic plan. My comment also relates to objective four under science and risk assessment goal, which we dealt with this morning, which I would like to see changed to include the recognition and acknowledgement of existing high risk food safety threats, as there are far too many which are not being acknowledged.

Page 8 of the plan states, "The limited existing body of knowledge about microbial contamination limits the ability to develop on farm preventive controls and systems of testing." While this may be true, as it is with all aspects of the food system, there is a vast amount of information which is known and ignored, including the basic

tenants of good hygiene.

Prevention is lauded as one of the guiding themes of the strategic plan. Yet the source of the vast majority of food borne pathogens is at the production stage. And the only way to actually prevent them is at this stage, yet there are no federal laws pertaining to the treatment of animals during production, and there is nothing specifically addressing preventive measures at the production stage in this document. Only the possible limitations are mentioned.

Until the plan contains provisions for regulating production practices, it will not genuinely be prevention based. And until production practices are regulated, people are going to continue to sicken and die unnecessarily.

MR. LEVITT: Thank you. Other comments along this row? Yes, please.

MR. SHIRE: My name is Bernie Shire. I am with the American Association of Meat Processors. We are going to be submitting some written comments on this, but I wanted to make just a few comments today, and specifically, on risk management, under objective one, where gaps exist in the current food safety system. And I was going to address the first action item, using risk criteria to determine where standards are needed to be harmonized between state and federal and among federal programs and develop a plan to meet those needs.

Years ago, the NAS and USDA FSIS put out some models that dealt with this whole question of risk management. And it is kind of a mystery. And no one knows what happened to those models. They were put out quite a long time ago. We think that

those models should be reinvented, or something similar to that because they set very precise goals for what the agency was going to do.

We feel that a single policy is needed in food inspection. And whether you are talking about one agency or another, I am going to focus on the two main agencies, FSIS and the Food and Drug Administration. There are two very different inspection systems. The FSIS has traditionally been a veterinarian based system. We traditionally looked at animal diseases. Today, of course, with animal health being improved and animals being safer, there is more focus on microbiological and science based inspection.

But there are many areas where the two systems inspect products that are not all that dissimilar, and yet they are a vastly different kind of inspection system. Under the FDA, as you know, there are many areas where inspection is carried out. And the regulatory means of inspection depends on voluntary compliance.

In a sense, there is very little inspection under FDA compared to the way USDA does things. And I guess the question you might ask is why is this. Are products regulated by FDA inherently safer than those regulated by USDA? Is seafood somehow safer than meat and poultry? I have been through some of the processing plants down Maryland's eastern shore. You are talking about crabs, and obviously one is not safer than the other.

And we think that the table needs to be evened. We don't think that meat and poultry are necessarily more dangerous than seafood or vice versa or any of the other products that is regulated by FDA. And we think that the council needs to take a look at

this and set up a comparative system where everything will be inspected on a risk based platform.

MR. LEVITT: And if I could just follow up, it if were harmonized, which system would you have it look more like?

MR. SHIRE: Probably in the middle, I think, a blending of the two.

MR. LEVITT: Yes, please.

MR. EMERLING: My name is Stan Emerling, and I represent the North American Meat Processors Association. Our members are processors of products. We have no slaughterers. We are dependent on raw materials that come to us upstream, which may be affected by pathogens or problems that we have no control over. We try to do the best we can with it. But we find in the end we are the responsible party.

So looking at this risk management goals, we want to talk about some of the different objectives here, one, two, three, and maybe all of them because they all incorporate somewhat the same thing. So rather than delineating one by one, I'll just sort of make a general exposition of what I am thinking about.

We would certainly congratulate the task force for the job it has done. It is a lot of work. I mean, it comes down to so many pages of paper, but it is a lot of work to be it out, and we appreciate your doing it. But the framework is almost like a motherhood issue. You really almost can't find any objections. You can pick and peck at it a little bit to try to tinker with it, which in a sense we are doing here. And many of the suggestions that have been made and the objections made have a validity, and I'm sure you'll

incorporate that.

But I think timeliness is important. I have been down here 17 years, and I'm just beginning to see something I was working on at that time come surfacing to the top. It isn't there yet, but hopefully, before I leave, maybe it will. So I am concerned that this instrument may well be a political type instrument. And when administrations or the substance of the House and Senate change, whether or not there will be any continuity to it -- I certainly hope that there will be. But I think that is something that we should all be realistic about.

I am concerned, basically -- and I know we have heard -- and I think Nancy Donley mentioned it, Dan Sowards mentioned it, about the overall risk assessment for all foods and to determine whether HACCP is necessary in those cases. And I heard HACCP risk analysis as opposed to risk assessment. And I don't know which would be the correct way. But I think that we need -- and they may be the same thing. But I do believe what we need is to take a look at where the problems begin.

They obviously, if you're talking about livestock, begin in the livestock. So somewhere down the line where it is appropriate to do it. And it would seem to me absolutely apparent that you would start at the producer level on the farm and take a look at it. Now I know that -- and we have had some complaint with the cattle industry not going far enough in opening their doors to some type -- and I'll use the word -- surveillance, you know, any of those things. I don't like to use the word HACCP, because that means a regulatory thing that may not be possible on a farm basis.

But all of these, or any of those, without action is all meaningless. And yet we haven't even attempted to do whatever this document continues to talk about, farm to table. But the table, we haven't even talked about it except for the word fork that Nancy used before. The farm we seem to skirt. Whether that is political because they have so many votes that you don't want to upset whatever apple cart there may be may be one thing.

But I hope that FSIS, in response to -- and I have raised this almost ad nauseam in every meeting about going onto the farm, and they are talking about now looking at veterinarians doing it. But we are continually told they do not have the authority. Well, when they don't seem to have the authority for recalls or civil penalties or to allow state inspection, they go to work and present legislation to do it.

I don't quite understand whether if they are being held back from looking at the farm for lack of legislation why they don't want to do something to do that. I think it would be appropriate. There may not be a problem there that we can solve. It may be some place else. It may be at the slaughter level.

I know that the only place it could be -- at least I feel that way about in our particular situation with our members, is if we would cross contaminate or add something to that process. But nevertheless, we are stuck with whatever we get coming from downstream, and something has to be done about that. And I would hopefully ask that you would take a look at legislation beyond what has already been proposed because if you need it, you should be asking for it. And then a long range plan that ignores a

problem is not really a viable long range plan, and there is a problem.

APHIS can't do it because it only can talk about the health of the animal. FSIS says it can't do it because it can only work at the slaughterhouse gate. And we have that gap there.

I would -- I need to look here just to see what I'm missing. I guess that those preventative type measures are the things that would be helpful, should be incorporated. We support performance standards. But those have to be drawn in a scientific based way so that we all can be comfortable that what is out there is something that can be met and is appropriate to be met.

I had some concern and expressed it earlier today about just adding, whether it be temporary or emergency or whatever, just without any reasoning at the spirit of the moment in the heat of battle. I think you need to look at it. You need some kind of emergency type approach that will carefully monitor. And I agree that sometimes you have to do things, and sometimes you don't have all of the science. But if we keep going that way on everything and don't find some way to make it more appropriate, that we are going to end up destroying the credibility of the industry in consumers' eyes.

So I would just respectfully ask that you consider these points. And we'll probably put them into comments and look at this a little further. There is a lot to digest here. Thank you.

MR. LEVITT: Thank you very much. Yes.

MS. SOSA: My name is Meryl Sosa, and I am representing Food Animals

Concerns Trust. And we will be submitting written comments as well. But I would like to address some comments.

I know I have mentioned this previously. I hope this is appropriate at this time. Regarding objective five, we feel that the statutory system must be changed. We feel that the current system is simply not working. And I think you only need to look to the situation involving the Supreme Beef Producers -- Processors case in Texas. And now we have a situation where, as a result of the Texas judge's decision in that case, Supreme Beef Processors is essentially free to put out contaminated meat without having any consequences happen to the company.

There is no point to having HACCP with performance standards if they can't be enforced. Thus we need a complete overhaul of the food safety statutory structure. We need a statutory structure that clearly and explicitly gives authority to the new food safety agency. And some examples of new statutes that we would recommend would be a statute that would give the food safety authority to recall products on its own without seeking voluntary action on the part of companies, authority to withdraw inspectors and to use other enforcement mechanisms to enforce HACCP without seeking court intervention.

We would recommend authority to obtain sales and use data from pharmaceutical companies and eliminate the right of pharmaceutical companies to claim that such information is proprietary. And finally, we would recommend that the new food safety authority have authority to withdraw old antibiotics from the market due to

antibiotic resistance concerns.

And now I would like to move to objectives one and six. We feel that regulations and statutes are needed, not voluntary programs. We do not feel -- and this is based on our experience with the egg safety programs and the quality assurance programs -- that voluntary programs work. First of all, voluntary programs are not uniform. They are not uniform amongst the states or amongst producer groups. There are -- the number of participants in each program is not known. And even if they are known, the associations are not disclosing that information.

The consistent -- we feel that consistency is of paramount importance to consumer confidence. Reliance on the states to help determine and/or implement food safety programs is problematic because different states have different agendas. And the standards should be uniform across the states.

The best case to look at is the case of animal waste. And I hate to keep bringing that up. But it is something that we are involved with. KFOs (phonetic) are a very good example because each state that has any regulations, those are regulations are different from state to state. And KFOs do look to the statutes or regulations that are currently existing in particular states before they decide what state to locate in. And you can look at Oklahoma. It is a very good example because at one point, Oklahoma wanted to attract KFOs, so they set their regulations at a certain level. And now, after a lot of experience with the KFOs and seeing what they ended up getting, for example, animals disposed of in improper ways, they realized that they really need to take a better look at

what is going on, and so they are.

But that is only one state. And we really need to have a national program where everybody is operating on the same level. And that way, neighbors can be assured that they are not going to all of a sudden have a KFO sited next to them, and that they are not going to be able to not do anything about it.

Also, we need to deal with the issues involving KFOs, such as odor. And those things are being dealt with right now in nuisance cases, and that is not really fair.

So finally, a couple of final items would be objective No. 4. We would suggest as an action item that objective four include monitoring water quality to determine whether there are on farm problems due to improper disposal of animal waste. This was not addressed by the manual issued by EPA.

And finally, objective one, action one, we would like to know who will determine what constitutes the risk criteria that are applied, and will consumer groups be allowed to have involvement in those decisions. Thank you.

MR. LEVITT: Okay. Yes.

MS. BILLAUER: Barbara Billauer, Association of Environmental Health Academic Programs. I'd like to call your attention to objective five, which talks about consistent training. Obviously, consistent training is going to be beneficial for everyone. It will enable state and local people to talk to each other using the same language. It will enable people across states to talk to each other using the same language and focus on the same issues.

I'd also like to see a similar concern for training up here in the risk assessment and the risk communication sections. It is somewhat odd that risk management focuses on training, but the other two cores -- I didn't see anything specifically broken out for that. So the emphasis for training is important. But what concerns me is what is this training program going to look like. Who is going to decide what the core competencies are and what the training elements that are appropriate for this group is going to be?

I have this nightmarish reminiscence of what was done by the EPA many years ago, I guess in the '80s, after the asbestos laws were passed, when five universities of eminent levels were contracted out to provide training to enable compliance with the NESHAPs laws at that time. And the professionals referred to those trainees as five day wonders. It was not particularly flattering.

So I am very concerned as to who is going to set the standards for the training? Who is going to monitor the quality of the Internet? Who is going to be available to answer the Internet questions? Will there be e-mail feed-ins? Will there be people at this agency who will be assigned to respond to the questions? How long is the course going to be? Who is going to teach it? What will the credentials of those people be?

The objective is wonderful. It is noble. It is important. But carrying out that mandate is not something to be taken lightly, and I don't think can be addressed in this one day session. But it is something that requires a lot of thought.

On a specific basis, in terms of risk management, I would like to remind the panel to consider comparative risks. It seems that every time we address one environmental hazard, we inadvertently create another. When we kill our hamburgers by cooking it, we might wipe out all of the microbes, and we are not going to die perhaps of some unknown pathogen. But we might later on die of some carcinogenic substance that is released when meat is charbroiled at high temperatures, which is a known risk factor for cancer.

The same concern can be addressed to cost benefit. Cost benefit is really comparative risk. Cost is a risk of a benefit. And when we start balancing the risks against each other, we might come out with a different outcome. I don't know what it is, but just the focus of balancing the risks of what our actions are need to be considered.

Specifically, though, on a regulatory -- Dr. Gabriel asked for specific regulations. There are some environmental statutes that prohibit cost benefit considerations. I think the Safe Drinking Water Act is one of them. I know there are several. There are others that mandate a -- require deep analysis.

So in some kind of -- it is possible to have some type of legislation which bans costs benefit analysis in the considerations and prohibits the OMB's invasive, time consuming analysis. I mean, that is not beyond the realm of possibility. And I finally want to remind people that the laws are flexible, and established regulatory requirements maybe should not be the be-all and end-all. We can change laws. We should change the laws if it is appropriate.

We shouldn't just throw up our hands and say, well, that is the law, we have got to it, if it is a stupid law, if science turns out says the law is wrong. And I think we should be mobilized to take it upon ourselves to change laws that are wrong. That is the beauty of our system, that we can change laws. Thank you.

MR. LEVITT: Okay. Thank you very much. Before I jump outside, it was hard for everybody to get back immediately from lunch. So why don't I do another quick round for people that have not spoken already during this session. Nancy Donley.

MS. DONLEY: Thank you. Nancy Donley, from STOP. And I apologize for getting back too late.

MR. LEVITT: It probably wasn't your fault.

MS. DONLEY: The risk management, I see a lot of potential in this area for some strengthening. And I just would kind of like to go over some ideas that I have. And this is not an exhaustive list by any means. I'll cover things more fully. But I would like to touch on a few things.

I kind of notice that there was not any mention within this area of incentives perhaps and penalties. And that is an area, I think, where FSIS has had some success in the past with putting in some sort of incentive programs, and that that is something that could be discussed within this area here of risk management. And it should not just -- and FSIS has done it in the -- of course, in the meat and poultry plants, primarily in ground beef products.

So I think there is an area there that is kind of right for opportunity.

MR. LEVITT: Excuse me. Just for clarification so everybody can follow, an incentive program, you mean --

MS. DONLEY: That if companies are -- in this case, if they were -- they met -- were meeting certain criteria, that they were not -- and I'm not -- the word exempt is not correct. But they would have less of a chance of having FSIS do their random sampling program for 0157:H7. It gave the companies an incentive to go back to their suppliers and say, listen, we want you doing the testing for it so that we are buying this product, in which case FSIS would concentrate their resources at companies that weren't doing those preventive strategies to begin with.

Back to gaps. The first objective, number one, I agree with Stan Emerling on this completely. We have always said that there is a gap there. And there is a gap in meat and poultry, the farm gap, prevention strategies. And it is the same thing for produce, producers of fresh produce and juices, and products that are used for juices. If that -- if in this identification of gaps, if the farm doesn't come up as a great big one, then someone has missed a sink hole.

So I also want to just say kind of as a general measure, too, that it is in this area, I think, that the council should apply a whole risk assessment to the entire farm to table continuum to best devise allocation of resources for risk management.

I just want to jump to a couple of objectives. Objective No. 2 then, action three, promote targeted labeling strategies to provide consumers the necessary -- the information necessary for them to feel confident in their selection of foods processed by

enhanced safety technology such as irradiation.

I don't know, unless it was just meant in the general conversation, but I really question -- there is also definitely a need for warning labels. And I feel that would fall -- under here, it is -- this particular sentence was made in a positive way to say this is what we are doing for you. But consumers also need labels that are telling them that there -- caution, this may not be good for your health. So there is definitely need for warning labels to be included in there.

One other, objection No. 4 -- objective No. 4, sorry.

(Laughter)

MS. DONLEY: Action two, which talks about reporting of identified outbreaks, safety risks, and violation of food safety standards to all appropriate federal, state, tribal, and local regulatory agencies for investigation and possible enforcement action. What is missing there is you made no mention of informing the public. And the public should be notified immediately in the process as well as to any sort of outbreaks and safety violations.

A statutory change here that is very desperately needed is this one of industry's -- what they call their proprietary information. The alerts that do make it out to the public don't go far enough. There is -- agencies are prohibited from stating what retail outlets have been carrying the food products. And therefore, what is happening is that consumers have purchased the products. It is sitting in their kitchens and in their homes. Or they have eaten it, and the recall is ineffective in getting to that level for them to further

protect themselves, to return the product, destroy the product, not to eat the product.

And it particularly doesn't make any sense -- and if we are going back to the vision statement, where everyone understands and fulfills their obligations. So this is a critical issue that needs to be addressed, is to get this proprietary information limitation taken care of.

And then just the last thing I want to talk about is objective No. 5. Again, this is the food safety agencies that just need to be able to have the authority to assess fine and penalties. And that is something that needs again to come through some sort of a statutory -- change in statutory authority.

So those are my comments. Thank you.

MR. LEVITT: Thank you very much. Dan Sowards.

MR. SOWARDS: Since we are talking about legislative changes that may be needed, particularly in this case on risk management, there are two that the AFDO board of directors had come up with. As we all know, or hopefully all know, the use of irradiation has been shown to be safe as far as the way it has been addressed by the regulatory agencies. At the same time, it has been very limited in scope and in use because the Federal Food, Drug and Cosmetic Act requires the FDA to look at it from the standpoint of a food additive.

The AFDO board believes that irradiation should be looked at as a process and not as a food additive. This is really tying the FDA's hands because I think they are currently faced with five or six more food additive petitions on irradiation. One in

particular is on ready-to-eat foods. So AFDO believes there needs to be a statutory change there.

The other issue deals with a subject that no one has broached so far today, believe it or not, and that is dietary supplements. Dietary supplements are foods by legal status. DSHEA, the Dietary Supplement Health and Education Act, eliminated the application of the food additive section of the Food, Drug and Cosmetic Act from applicability to supplements. And AFDO understands the rationale there.

However, DSHEA also tied the federal agencies' hands in being able to examine the safety data that the industry companies have to document the fact that their products are safe prior to marketing. Now AFDO is not advocating that FDA be reinstated the authority to review to the extent of food additive status. However, we do believe that the statute needs to be tinkered with enough to allow FDA access to that information, to be able to view what information companies have to document the safety.

The act does require companies to have information on hand to document safety of the products. We feel that FDA should have that authority to examine that information to see if companies indeed do have information in this area.

MR. LEVITT: Okay. Thank you. Just on the subject of dietary supplements, when the task force got together -- I'm going to say a year or so ago by now, when the process began -- we looked at what we thought the core jurisdictional issues ought to be -- not jurisdictional, but product issues ought to be. And we were all in agreement that it ought to go beyond microbiological hazards to chemical hazards,

physical hazards, food additives, and so forth.

We did draw the line just before dietary supplements, not because they don't raise important issues but because they raise a lot of different kinds of issues, and we wanted to try to keep the focus here on the rest of the conventional food products.

MR. SOWARDS: You didn't want to confuse us.

(Laughter)

MR. LEVITT: But thank you.

MR. SOWARDS: The only other comment I would make is that in the initial Federal Register publication, one of the bullets talked about partnerships with the states and locals. And the word partnership was specifically mentioned in that bullet. I didn't actually see, and I may have overlooked it, the term partnership in the draft document. And I would suggest that that be added in there, particularly under risk management.

MR. LEVITT: Okay. Thank you. Other people that did not get to speak in the first round? Yes.

DR. WOTEKI: May I ask a follow-up question on that.

MR. LEVITT: Please.

DR. WOTEKI: Dan, I think that is certainly -- from the discussion this morning, the whole issue of interrelationships among the different levels of government is one that we will be again going back and taking a look at. But could you define what you mean by partnership because?

MR. SOWARDS: Sure.

DR. WOTEKI: Because that, I think, is also an integral part to this. And there are many different senses of the word partnership.

MR. SOWARDS: Well, I think partnership involves a number of different things. It would involve adequate oversight, for one thing, if a partnership were to be agreed upon between the federal agency and a state or a state and a local agency, to ensure that there was adequate implementation of the regulations. In this case, we are talking about risk management.

In addition, there would have to be adequate infrastructure and adequate regulations that the state would have to have in order to implement a partnership. And to answer your direct question as far as what a partnership would be, it would be an agreement between the agencies that there would not be duplication of the use of resources to conduct a particular function. If we are talking about inspections of, let's say, a particular industry, maybe a partnership on seafood inspections, that in this case there would be no duplication.

It may mean sharing the inventory to where FDA would inspect 80 establishments, the state would inspect 80 establishments. And perhaps the next year they would flip flop. But it would mean -- or it could mean that the state is going to do all of the inspections of, let's say, low acid canned foods. In Texas, we have such an agreement.

So it could mean several things. But the partnership in effect would mean the elimination of any duplicative activities.

MR. LEVITT: And in that case, do the federal standards still apply?

MR. SOWARDS: Yes. The federal standards would have to apply, simply because the federal agency would have to know that their standards were being met.

MR. LEVITT: And your concept before of federal oversight would also apply in that setting?

MR. SOWARDS: It most certainly would.

DR. WOTEKI: And where would the resources come from? Would the state provide all of the resources for its part of the partnership, and the feds would provide --

MR. SOWARDS: I think it would depend upon --

DR. WOTEKI: -- their part of the partnership?

MR. SOWARDS: -- the particular situation. For instance, if the state had the capabilities, they had the training, they had the infrastructure, they had the laws and regulations, but perhaps lacked the equipment, then it may be a situation where the federal agency could supply computers, field inspection equipment to enable the state to be able to do the job in an efficient manner for the federal agency.

So -- but for the most part, it would not necessarily mean -- partnerships don't mean contracts, in other words. So it would not mean that the federal agency was paying the state to do the inspection. Contracts is a totally different concept.

MR. LEVITT: Okay. Thank you very much. Yes, next.

MS. ZAWEL: Stacey Zawel, GMA. I have got just a couple of comments

under this section, one of them being the -- under objective two, the last line, the last section that Nancy Donley noted, which is with respect to promote targeted labeling strategies such as irradiation. I think irradiation is a pretty example to use since in fact it has resulted in lack of use of irradiation because consumers are so alarmed by the technology, and so that we need to recognize that fact in the development of any further labeling strategies, so in fact that they don't deter implementation of the technology that can actually help.

Under objective seven -- actually, I want to combine kind of objective five and objective seven with respect to training of inspectors and new technologies, or let's little understood existing technologies. Somewhere in there, we should note that we need to incorporate new technologies and these existing technologies into current inspection processes.

What I mean by that is to include training of inspectors about the new technologies and about some existing technologies. And an example is something that, Joe, I know you are involved in out in Minneapolis next week, and that is something that GMA members, along with the FDA's commissioners office have put together a training program on ALIZA (phonetic) methods. And really, what it does is it brings the inspectors into a food facility, shows how they are going to be used, gives an opportunity for a give and take. And I think, you know, it is something that we would definitely like to expand upon and is a good example of something that could be included in here as a broad mission so that our inspections can be effective.

Then under objective eight, the third action item, where it says facilitate a seamless local, state, and federal response system, what I would recommend is that the wording gets changed, not because the words are so important, but the spirit behind the words are important. And that is that it could note, "Develop national protocols for initiating and conducting source tracing and recalls and for assuring timely and accurate communication with industry and with the public during those recalls," taking out "adequate" and making protocols also refer to assuring communication as well.

And then just in general, with respect to objective nine, I think in principle the goal of addressing international food safety standards is something that we need to work towards. But in terms of setting priorities, focusing on our domestic activities is probably -- needs to be done first. Thank you.

MR. LEVITT: Thank you very much, Stacey. Yes.

MR. STEINHOFF: Under objective four --

MR. LEVITT: Again, even if we spoke before, we could identify ourselves.

MR. STEINHOFF: Oh, I'm sorry.

MR. LEVITT: That's okay.

MR. STEINHOFF: I'm sorry. I'm Steve Steinhoff from the Division of Food Safety at the Wisconsin Department of Ag, and also on the board of AFDO. The first action item, under objective four, talks about prioritizing inspections based on risk. And, you know, just to hitchhike on a topic that was brought up a couple of times before,

is to do this risk analysis to determine whether or not to go forward with HACCP. That is all well and good, but I guess my reason for bringing it up again is really the value of that gets into issues of authority and budget and getting out of your box or your silo or your agency or whatever it is at whatever level of government.

It goes back -- I was reminded when a gentleman from the meat industry spoke a while ago, I have a meat program in the state of Wisconsin. I get to listen to that industry talk to me about how many times our meat inspectors come in versus how many times our food inspectors come in, and woe is us and why aren't we more level.

Ideally, ideally, this risk evaluation step should tell us where we should put the resources. But then we immediately do, of course, if we only reallocate those resources or get more resources within our agency or our system, the volume of that is very minimal. When we try to go beyond that, though, we immediately hit the constraints of authority and budget and tradition and lots of other things. So, you know, that is all there. I mean, it is a great idea, but the -- we bump into the practicality right away.

The other piece I would add to that first item would be the issue of once you have done this ideal system that is focused on risk, is to then layer on top of that performance. We have done that in one of our inspection systems. While it is conceptually a very good thing to do, practically it even works. And that is if you have an operator, once you have decided where the norm is for them on a risk basis, then if they are a very good operator, it is an incentive, if you will. They have the benefit of not seeing us regulators quite so often.

They operate their system. They operate it well every day. Why should we be there, which, of course, that allows us to free up resources to spend a little more time with those who don't quite get it at the other end of the spectrum. So I'm a great proponent of that and would suggest you think about that piece.

I do have a couple of other points. In objective seven, I would suggest you add another action item. And it has to do with the handling of innovations. And this is one that we all deal with. And I'll just give you the rough wording I have. It is develop a system to evaluate and record decisions about food safety aspects of proposed food production processing, food processing production, or food handling innovations.

It is the issue of -- you know, in some worlds it is called variance. But we set a standard, a minimum standard or a best practice. But when somebody -- you know, the world is not static, and statutes and regulations are a little bit, and that is the way life is. They always follow innovation. But we have to be able sometimes to deal with those things in a somewhat rapid and uniform manner and record what we have done for others so that we aren't all over the place because uniformity in the grand scheme of things is a very large issue. So we need a system to handle that.

And finally, under objective ten, the first action item talks about evaluation and the management of food safety risks. Here I don't mean to quibble. But I think that the monitoring of your system should be done continually, not periodically. You need to have a system that monitors things continually based on critical performance factors that we would all agree on, and we being all of the regulators and the industry that is being

regulated, and that we evaluate them quite frequently.

Now once we have that, you know, we use that then to reprioritize what we do. We use it for budgeting purposes. We use it for all kinds of things internally. And the industry can then also use it, you know, if we often get in these little quibbles and meetings about -- and ideally, it is the industry that are the keepers of food safety. And there is some talk that, yeah, they have good inspection or good safety systems. But if you had a system like this that monitors performance, sometimes you can say to them, here is a place where it isn't working so good, you know. Here is -- we will do some things as regulators with this data, but there is value in that data for the industry also. Thank you.

MR. LEVITT: Thank you very much. Caroline.

MS. DeWAAL: Thank you. Caroline Smith DeWaal, Center for Science in the Public Interest. Where to begin? I think I agree with the people who think that this section needs significant revisions and significant strengthening. I am not getting from it a coherent policy yet. And maybe -- I mean, I have read it over several times. But I'm still not understanding quite how what is written down here is going to impact some of the current systems.

For example, you know, we have pizza plants regulated either every day or once every ten years depending on whether they have pepperoni on the pizza. How is this strategic plan going to address that? Shellfish plants, one of the most hazardous foods in the U.S., are never visited by federal inspectors. It is totally inspected by the states under

these partnerships or agreements or whatever you want to call them. But the reality is the federal inspection -- they may audit plants on occasion, but they are not there regularly inspecting.

Egg safety, we have heard a lot about that today. You know, how is this strategic plan going to address the fact that to get an egg safety plan out of the U.S. government took the consensus not only of all the government people in this room practically, but of two cabinet level secretaries.

Imports, how is this strategic plan going to address the fact that FDA inspects all meat and poultry products that are imported into the U.S.? They have gone to the country. They have audited the foreign country's program. They have gone and visited individual plants before they allowed to ship product to the U.S., a very comprehensive system for importing meat and poultry. For FDA regulated foods, there is no comparable system. There is nothing. FDA inspectors are understaffed and inspect less than 2 percent of food products.

How is this plan going to deal with that? Where is it? I'm not seeing it yet. HACCP, we have a HACCP system at USDA that includes continuous inspection or carcass by carcass inspection and mandatory microbial sampling, both by the industry and a government program. Seafood, it is -- we have done none of that. We have, you know, inspections maybe once a year and no verification, mandatory verification component. Again, if I am missing something, please let me know. But I do not see in this document how this is going to address that.

High risk -- I want to turn to something that is in the document, where you say on objective four you are going to prioritize for inspection those categories of foods determined by risk assessment, which may take another ten years, to pose high risk to consumers or to public health. What about the other foods? The public thinks you are looking at everything. I mean, let's face it. The public has a very high expectation here. They really think the government is checking the food.

In the case of meat and poultry products, they are right. Whether it does much good in some instances is another question. But they're right. The government is checking the food. But what about low risk products? What about medium risk products? What about products where we don't know whether the risk exists or emerging hazards? The government -- the customer, the consumer thinks you are inspecting the foods.

I am deeply -- I am really troubled by the focus here on prioritizing for inspection high risk foods. You know, if you want to make risk decisions, that's fine. But the consumer wants a coherent inspection policy, and it is not, at least from what I can read or look at this document, I don't see it.

We talked as being were going around that end of the table about whether we need legislation. I don't see that the changes that need to be made can be made without consolidation of the food safety system. Whether, you know, you have a series of things at the end of the document on approaches to consolidating food safety structures, ranging from, you know, leaving everything the way it is and better coordination to having

a lead agency to maybe having an inspection agency. And I think that is a valuable -- I'm glad that is a part of this document. It is the first time I have seen a serious discussion of just even kind of what the range of options are.

I think in the final document, the President's Council not only needs to answer the questions posed on restructuring government by the National Academy of Sciences report, but you also need to address the gaps which are identified by legislation such as the Safe Food Act, which calls on you to consolidate the food safety functions, and by the Consumer Food Safety Act, both filed -- one by -- Safe Food Act is by Sen. Durbin, and the Consumer Food Safety Act by Sen. Dorgan.

These bills point out the gaps which have been identified by Congress. So I think in the final document, you need to really be much more specific about how the strategic plan is going to address the current gaps, not just identifying gaps. Gosh, we have been doing that for a couple of years now, but actually addressing the gaps as they exist today. Thank you.

MR. LEVITT: Thank you. I think about when we came around this side is when there were more people in the room. But is there anybody that didn't get a chance to speak before at the table? Yes.

MR. COLETTE: Robert Colette, National Fisheries Institute. We were going to have comments throughout this particular section of the document. But I would like to focus some brief comments on objective No. 9 with respect to imported food safety. And I would like to compliment the plan in one respect, and then mention

something that I think is missing.

MR. LEVITT: Don't worry. You won't be punished.

(Laughter)

MR. COLETTE: First of all, the first action item discusses the need for strengthening assessments of foreign systems and conducting additional assessments of the reformed regulatory food safety programs. And we applaud that. And the fish and seafood industry, under the HACCP rules, our importers are required to have importer verification programs that establish product specifications and then sometimes some type of affirmative actions to verify the HACCP rules are being followed in those countries.

Those efforts certainly can and should be augmented by more federal oversight. And we do know that FDA has made some visits to key countries around the world to begin looking more closely at how they are implementing HACCP for fish and seafood. And we are pleased to see that that is increasing, and there will be a larger number of countries visited in the future. So we applaud that effort because we do think it is important to plug that into the fourth action item, which talks to improving and expanding where needed risk based port of entry inspections.

I think the realities are that there are limited government resources in order to do that. So really, it does have to be a risk based and sensible approach to looking at port of entry. We can't come close to looking at all the products coming into the country. So we really should be focusing our attention on a risk based approach knowing where the greatest problems could occur. So we do applaud that.

What is missing from that equation, the way I see this, is that there is no mention whatsoever of equivalency agreements with other countries. Maybe that is in here implied in some fashion. But I think that is a -- I think that is missing from the plan. The food inspection authorities in some of the countries are very, very effective and have very good programs in place. And I think more needs to be done in order to evaluate those and see if they are unequivalent with the U.S. stance. And then we can 266 move on and focus on those other places around the world where they are not on the same level in the food safety continuum.

Lastly, the word "improve" is used to use -- is used in the fourth action item in terms of improving the system. One part of improving the system is to focus on a more risk based approach and to take a closer look at the foreign programs. The other part of improving has to do with the system that is in place here in the United States. The efficiencies is, to our observation, not what it needs to be. If improvements could be made in the efficiency of the system and it became a more timely and -- a more timely system that got through and looked at the products very quickly and efficiently, I think you would see a greater level of cooperation in the import community, and therefore a higher level of compliance. Thank you.

MR. LEVITT: Thank you very much. Yes.

MR. HODGES: Jim Hodges, American Meat Institute. Throughout this document, particularly in the risk management section, it seems heavily weighted to such things as talking about monitoring surveys, inspection surveillance, and a variety of other

areas. I would submit that we ought to be emphasizing more some of the concepts that are contained in objective two and talk more about prevention types of systems.

Clearly, no inspection system or testing program is going to improve the safety of the product itself. It is in the manufacturing process and the preventative measures you use in that manufacturing process that would enhance food safety. So it seems to me as a first point that I would try to emphasize prevention throughout this rather than simply monitoring detection or diagnostic types of things.

Secondly, also related, I should emphasize objective two in the prevention side of it, that the second phrase of that, I think, needs to be qualified. Where you are talking about establish national standards, including performance standards where appropriate, standards can be very appropriate for various circumstances. But we need to be very careful when we establish standards that they are in fact based on the public health outcome.

Many times I think standards are established at some interim level, and that may in fact not directly correlate to the reduction in human illness that may occur. So if you have an ultimate measure and you can put whatever term you want on it, whether it be a performance standard, a regulatory standard, a national standard, it seems to be that we need to emphasize, more so than some number, some arbitrary measurement, we need to emphasize the public health outcome as our major performance measurement.

Third, in that same area -- I think Stacey alluded to it earlier -- the action item number three, when you are talking about promoting targeted labeling, labeling

strategies, that, I believe needs to be rephrased somewhat in that we ought to target labeling strategies that are informative to the consumer where there is material and significant differences that may exist in the product.

If we go down the path of labeling every type of process, technology, innovation, and so forth, then we have a label that becomes either meaningless, or that label is so complicated and unable to contain the information that provides useful consumer information. There are many analogies that can be put on the table, but does the consumer want to know, for instance, that the milk that they drink was derived by machine or was it hand milked? I mean, you can go down that path so far when you are talking about labeling processes rather than labeling what is in the product that we get to the point that I think it becomes totally confusing and meaningless.

And the fourth point I would like to make is on objective four, action item one. You say prioritize for inspection those categories of food that pose a high risk. And you use examples, obviously -- I am going to do it from my heart -- meat and poultry and other products. I would submit to you that those examples are inappropriate across the board because if you use meat and poultry as an example of a high risk product, I would suggest to you that canned meat and poultry that is sterile on the shelf is one of the lowest risk products that we have available.

So it depends more on how the product is produced and what the ultimate outcome on the product is than the category of the product that is there. And that can be applied on eggs, seafood, ready-to-eat items and everything else. So I think it is clearly

inappropriate from my point of view to characterize food groups as being high risk or low risk. It depends on how those foods are processed and whether they meet some kind of criteria of safety. Thank you.

MR. LEVITT: Okay. Thank you. Let's go to the outside. We'll start back in this corner. Anybody from this table moving along in this direction? Yes, please.

MR. GREENBLAT: Jessie Greenblat, state epidemiologist in New Hampshire and a member of the Council of State and Territorial Epidemiologists. I would like to go from these rather larger issues to a more focused comment specifically on objective eight. Over the past year, we have had a number of discussions regarding the issue of trace backs and a recognition of the difficulty with this, but particularly multistate outbreaks in different agencies not stepping each other's toes and respecting the variety of needs of both epidemiologic as well as regulatory needs for trace back activities to occur.

I would just to suggest that under the action item, "Facilitate a seamless local, state, and federal response system," that the words, "Develop national protocols for initiating and conducting source tracing," be separated as a separate action item, and that the words, "For epidemiologic and regulatory purposes," be added in there, added to those statement to distinguish the dual roles that trace backs can serve. Thank you.

MR. LEVITT: Thank you.

MR. MITCHELL: I wanted to comment on the -- there is reference made --

MR. LEVITT: Sorry. You need to identify yourself.

MR. MITCHELL: Burt Mitchell, from the Center for Veterinary Medicine, Food and Drug Administration. There was a comment earlier about authority for on the farm inspections. And I wanted to clarify for the audience and the record that this authority exists under the Food, Drug and Cosmetic Act. It has been upheld in federal courts. We regularly follow up on volative residues, either through the use of FDA inspectors or state inspectors who are under contract or some other informal agreement with the agency.

That is a federal authority under the Federal Food, Drug and Cosmetic Act.

MR. LEVITT: Okay. Thank you. Other -- yes, Stu Richardson.

MR. RICHARDSON: Stuart Richardson, California Department of Health Services. Just a follow-up of this morning's discussion and again this afternoon again about this -- the application and the utilization of all the resources dealing with risk management specifically. In the document, it talks about coordinating these resources in the narrative. As you heard from previous speakers, it was mentioned that there is a need to do more than just coordinate.

I would recommend, as a suggestion anyway, another -- an objective, a specific objective in this whole area. I believe we in the states feel very strongly that oversight, a minimum bar requirements, all of the things that were said earlier this morning, not to repeat them again this afternoon, are enthusiastically agreed to by the agencies and the states who have resources that they want to bring to the table.

As such, it seems to me that a specific objective along the lines of

establishing minimum program resource oversight and evaluation standards for all programs at all levels of government be entertained as an objective with specific action items behind that to bring to the point that we are not talking about a federal agency abrogating or just giving away its authority, but indeed, establishing a national bar that all the resources that want to be brought to the table must meet.

It seems to me that it's best said if there is a standard setting process of minimal requirement, we have other models for that. EPA's small water program, EPA's pesticide primacy program, NRC's -- logical health program, in which programmatic standards, auditing, personnel standards, numbers of people to inspections, field auditing, are all there, in which they are assured that the resources are being applied to the most important aspects and applied in a very diligent and effective way, not being influenced by outside parties, but being influenced by the needs of the program. Thank you.

MR. LEVITT: Thank you. Other comments along this side, back corner? Yeah, the side right here.

MR. KAY: Bret Kay, with the National Consumers League. And I would just like to, I guess, start with objective one, where it is, "Identify areas where risk management exist in the current food safety system," and then under that the action item, "Build the infrastructure required to support a seamless federal, state, local food safety system.

We are concerned that there isn't this seamless system currently, and that there really needs to be. As the gentleman from AMI pointed out, it is not what he said

necessarily, it is the food that is at risk, but the way the process is. And we feel if that is the case, then they should be regulated and inspected and monitored the same. All the food should have a consistent system so that there is equal resources and equal regulation on all food products that are currently regulated, whether it be FSIS, USDA, FDA. And we feel that currently that is not the situation, and that is what is causing major gaps and some problems.

It just doesn't make sense that FDA is inspecting food, seafoods, and pizzas with cheese one way, whereas the USDA is inspecting meat and poultry and eggs in a different way. And it is just that those gaps nearly need to be closed and that there needs to be a more unified and single food safety system that really addresses the risks in a unified way.

MR. LEVITT: Thank you. Across the back, anybody I didn't miss over here again, across the back? Yes, please. And just to give people a read on the time, we have about 15 minutes additional allocated for this part of the program.

MR. PARK: I'm Doug Park, with Michigan Department of Agriculture. And in addition to serving as a coordinator for outbreaks and trace backs, we also have the recall coordination activity in our office.

I wanted to talk about objective four and objective eight very briefly. And I would like to endorse what Ms. Donley said earlier, and that is that our agencies are hindered indeed when the proprietary information is not provided to the state agencies. And we do not have the location in which the subject product is on a shelf. And I know

FSIS is currently studying that issue, and we expect some information to come out shortly. But if that could be expedited in some fashion and not be held up with this open forum, it would be appreciated. And perhaps that is also something to reference on our objective four long term.

With regard to objective eight, the last two action items deal with the issue of electronic information sharing. But it may be in its verbiage -- it may be a little too narrow focus because in the process of state agencies needing to acquire data, it is not only the public agencies at the state level, but it is the state and agriculture agencies at the state and local level that need to acquire that information. And if we were to open up the focus a little bit, we might want to say something to the point of designing and developing information sharing systems that are acquiring data for -- and sending data for state and local agencies.

And also, you would want to expand the impact beyond outbreaks to also include trace backs, something that this gentleman over -- I think it was Jessie who referenced trace backs as well. So there may be a need here within objective number eight to tie our trace backs and outbreaks a little better. Thank you.

MR. LEVITT: Anybody else across the back of the room? Moving along to the left side. Yes, please.

MS. MURANO: Elsa Murano, Texas A&M University. Objective No. 9, where we are talking about foods that are exported to the U.S., even though I know we have a lot of things to resolve here in this country, we have to definitely consider this as an

important objective in the strategic plan. I'm very happy to see that area addressed here.

What I would like to point out very, very briefly since we are running out of time is action item No. 3, where we are suggesting that we should provide technical assistance to these countries and so forth and so on. One thing that I don't see in here is the role of academic institutions. We in Texas and certainly in Florida and some other states that are very close to Latin America have very active international programs where we have the capabilities, the know-how, and so forth, the countries have the need.

What is missing is the resources to deliver that. And if we could enter into partnerships with the government to help us deliver those training programs to Latin America, that would help tremendously. So I think it is important that we include there the academic institutions that are well versed in this area. Thank you.

MR. LEVITT: Thank you. As an aside, can I just comment, it is refreshing to see a number of academic representatives here. I think too often it is an important part of the community that we don't bring in as closely as we would like. Yes, please.

MR. JONES: Good afternoon. I'm Ben Jones. I represent AAFCO, the Association of American Food Control Officials. And our membership is comprised primarily of state feed regulatory agencies whose responsibility is the regulation and enforcement of the state feed laws. Their regulations and portions of the food -- the Federal Food, Drug and Cosmetic Act.

One of our main purposes is to promote uniformity across the states in the

feed regulations regarding labeling ingredients, terms and definitions. And that would include the protocols for animal waste feeding as well. But the Food, Drug and Cosmetic Act defines feed as food. And this document references food repeatedly. We are a little unclear as an association as to just where feed is going to fall in this document, and if it will follow that definition as set forth by the Food, Drug and Cosmetic Act.

We have been developing our own food initiative, food safety initiative, for the past two years in the organization regarding inspection enforcement and compliance regulations. And we just want to make sure that we are utilizing our efforts and our resources best, that we are not getting into duplicate efforts. And we would like to just know where you perceive our association and state feed regulatory agencies involved in this.

I guess, finally, I would like to reiterate under objective three, action five, where you state the development -- "To develop a network of animal diagnostic laboratories to enhance national systematic monitoring in animal feeds and feedstuffs for the various risks," we feel like that is what we are already doing. And we have been doing it for a number of years. So we are little unclear about that action item as well. Thank you.

MR. LEVITT: Okay. Thank you. Yes, next.

MR. LERMAN: Yes. Dion Lerman, Drexel University, Food Safety First. In looking over the plan, I was initially delighted to discover objective five, which is all about training, and then distraught when I realized it was only about training inspectors,

and that in fact no place that I can find in here does it talk about training anybody else. I already mentioned earlier, and Jim Mann from Health Minder mentioned, that food workers, food handlers, are critical to this. They are our -- they are important food protection agents. And we need to be taking them into consideration. We need to be providing training.

This document doesn't even reference current management certification and training, which is not national and not uniform, and in my belief should be. In another meeting in this same room about three months ago, the National Advisory Committee on Microbial Criteria for Food heard several speakers speaking on the issue of handwashing who pointed out that you need a license to drive, barbers need a license. Food handlers in most jurisdictions do not.

However, I would point out to you that in some jurisdictions, they do, and the program has not been an administrative nightmare, and in fact has been extremely successful in implementing. And I'm not sure where to stick this because, as I say, five is all about training regulatory personnel. It is certainly not six because six is about voluntary programs, and I believe these should be mandatory programs. Maybe it goes under objective two, development of preventative techniques because training is certainly preventative.

A final comment on the statutory question. In this case, I am going to speak out of my hat for myself, in that I -- I was supposed to be representing an organization. I believe we need a single unified food inspection and regulatory agency

that should be separate from both research and from an organization that would be promoting and marketing foodstuffs.

DR. WOTEKI: Can I ask a follow-up question, Joe? With respect to your comments about lack of emphasis on training, in the risk communication goal, there is a specific objective on developing state of the art science based education and training programs for the entire farm to table continuum, are you saying that it is not appropriate to have that objective under risk communication, it would be more appropriate to have it under risk management?

MR. LERMAN: Yes.

DR. WOTEKI: Or are you saying that you think it should be in both places?

MR. LERMAN: I think risk -- I think it is critical to be viewed as part of risk management. It is a preventative tool. It is not just a matter of communication. Somebody earlier pointed out, we want to change behavior. Simply having people regurgitate information isn't enough. And those of you who that have heard me on my soapbox before may know that I feel that this is actually a problem with the food code as it exists with the demonstration of knowledge because all you are really asking people to do is whether they can regurgitate the food code.

What you are not finding out when you ask people -- when an inspector goes in and asks for demonstration of knowledge -- is whether in fact there is a change in behavior in the way -- in safe food practices of the establishment. And I think that is really

important. In that objective that you mentioned about communication also, if there is this whole list of audiences, food handlers are not part of that list. They are implied as part of the farm to table continuum. But they are in fact not listed there.

DR. WOTEKI: Okay. That's a good point. The second follow-up question, with respect to your second point on organization -- and I'd like to also address this more broadly to the group. In this document is a fairly long listing with some description of different organizational --

MR. LERMAN: Option 5, No. 2.

DR. WOTEKI: Okay. Thanks.

MR. LEVITT: Okay. We have a few more minutes. Oh, yes, over here.

MR. MARTINEAU: Damian Martineau, American Culinary Federation. I just wanted to point out, I guess, a few things under risk management under the first objective. I think there ought to be an emphasis on focusing on a lower level. I kind of echo the sentiments of Dion over there that basic level food service workers are really not being addressed, and they are the front line people. Those are the people touching the food last before it goes to consumers, at least in the restaurant and food service industry, which is the second largest industry in this country after the government.

I think there ought to be a lot more focus on that, on training these people. Most of them are entry level workers in the work force, that language barriers are big problems. There are a lot of issues there related to that. But nevertheless, these people need to be trained because you are subjecting the public to what their standard is. And if

they are not taught to a certain level, how can you expect that the person who is eating the hamburger or whatever it is you order in the food in a restaurant is actually safe.

It is one thing to have managers and owners of restaurants and so forth certified and educated about this stuff, but that information has to flow down to the people who are actually producing it. And so I really don't see that addressed in this document either, as Dion just pointed out. It talks about a lot of the federal workers and inspectors getting certified and credentials and so forth. But it really doesn't address the actual people who are producing.

There are organizations who do certification, I mean, on all levels, even for chefs. My organization does certification. So does the Restaurant Association and so forth. And maybe those organizations need to be tapped and a uniform system should be developed, at least for a minimum level entry level certification or licensing or whatever you want to call it.

I mean, you are dealing with a very delicate situation in terms of food safety. But we have licensing and credentials for hairdressers, for example. But we don't have it for cooks. So, I mean, we always -- even as chefs, we always question why that was. That seems to be a gap in the system, you know, that, I mean, if they cut your hair a little too short it is no big deal. But if somebody puts tainted mushrooms in the sauce, you could die, you know. So I really think that needs to be addressed here in this document.

As well, I really don't see any mention -- and I'm not sure if it is taboo or what, but I haven't heard anything about biogenetics and bioengineering. And for us, we

see that as a real risk. I mean, I don't want -- if I am going to make a tomato sauce, I want it to taste like tomatoes. I don't want it to taste like chicken or something else.

(Laughter)

MR. MARTINEAU: I mean, I'm just maybe going overboard with it. But it could get out of hand, and I don't see any control mechanism in this document either, you know. There are a lot of sensitive areas with regards to that, and I think that ought to be addressed because it is a matter of food safety. If somebody has an allergic reaction to nuts, for example, and somebody feels that a nut gene is going to make the tomatoes last longer when they are shipped, and they put that in there, we need to know that because we don't know what the reaction is going to be. So, you know, I think the document should address some of those things.

And the last thing I guess I have is that I certainly support the preventative approach because, again, we are kind of an end user of the product. And I think somebody spoke about the meat processing business and they're getting cattle and so forth. They are kind of a middle man. We're definitely way down the line on that, and we certainly don't want to face the repercussions of dealing with foods that we have no control over in terms of their quality in the developmental stages, you know. It is one thing if we overcooked it. But, you know, it is another thing if it is tainted. That's it. Thanks.

MR. LEVITT: Okay. Thank you very much. There were three additional people that have signaled, maybe four additional people that have signaled. So let's try to

do them, let them speak, and then we will probably, I think, plan to take a break. We'll start at the back mike, and then right up here at the table, and then these two gentlemen at this table. Just because they sat in this corner, I don't want to shortchange them. Please.

MR. HOLMES: Scott Holmes, chief of the environmental health division of Lincoln Lancaster County Health Department. Very brief comments related to objectives four, related to inspections. I would encourage that their be an additional action step added relative to the use of electronic inspection software, and would encourage FDA -- this is on the retail end -- FDA to not only develop that software, which I know they are in the process of, but also support that software long term with updates and changes.

The new food code is very cumbersome to work with. The biggest complaint that we have had from our field staff in working with it is how difficult it is to work with because it is so detailed. And with the new approach to inspections, it does not include a check-off type box format. They are writing down every single section of the code that is violated and the violation and the correction by hand on every inspection.

That has increased our inspection time by 15 to 20 percent for every inspection, and that was something we predicted and told our board of health and city council and county board that that would occur, and that is in fact exactly what occurred. We have the data to show you. And so an efficient method to reduce some of that would be to develop the electronic inspection system and enhance that. I know that is in place. But I'm concerned that it is not mentioned anywhere in this plan. And, obviously, it won't

be budgeted if it is not planned. So thank you.

MR. LEVITT: Thank you. Do you have follow-up?

MS. LAUTNER: Beth Lautner, National Pork Producers Council. Yes, I had one comment on objective seven, and then it feeds into my comment on objective six. But I think we need an action item under objective seven that talks about facilitating access to research results. Sometimes the results are not -- result in something that is licensable or patentable, but it is information that can be applied. And I would see that application into objective six when you are talking about using research results then to develop best practices or good production practices, specifically at the farm level as well.

And I think it is important to understand that the research is a critical part of on-farm development of production practices. We are still having confusing research results out there that we are trying to take and develop into good production practices.

I will give just one example. We have conducted research in feed withdrawal that shows that there is less problems with evisceration techniques if you withdraw feed. However, in three other studies, we have shown that you can either increase salmonella shedding, decrease salmonella shedding, or have no effect on salmonella shedding with feed withdrawal. But you can also increase campylobacter shedding with feed withdrawal, and you can raise animal care concerns as well.

So we are trying to work through those types of issues. And it is going to be very important to have research results very forthcoming to help us. Also, I would glad to hear Dr. Mitchell clarify. We have been telling our producers, and they operate under

the fact, that FDA has on farm authority. And I was glad to see him clarify that because that is what we have been telling our producers.

MR. LEVITT: Okay. Thank you. We have two other comments over here, and then we'll close out this session.

MR. WHITNEY: I'd like to speak very briefly to objective five and objective seven in the practical application. And I will speak as a past member of American Culinary Federation, a past culinary educator, to say that more and more of the food that is being consumed in this country is being consumed at and being prepared at for off-site consumption at commercial restaurants.

You cannot assume that the people preparing the food are going to make the connection between a general, abstract communication about food handling, and how they operate on the job unless you provide resources and incentives for the actual cooks, many of whom don't come from our culture, don't share our notions of proper sanitation, don't speak English as a first language. They will not make the connection between general communications and what they are doing on a moment to moment basis in the pressures in the operational kitchen. You have to provide practical, on the job risk management oriented communication in place, not in general.

By the same token, if you do not provide incentives for better equipment in the kitchen to observe safe food handling, the comment was made earlier about undercooked burgers on a griddle with uneven heat. There are no financial incentives in many kitchens, particularly those with state or federal funding, to invest in high quality

equipment. Lower quality equipment will not perform consistently. And knowing that I should cook that burger to 160, as the gentleman from ACF pointed out before, if I am doing a banquet, I'm not going to temp every single hamburger.

Unless there are incentives or better education in place in the kitchen and financial incentives to improve the equipment in those kitchens so they can operate, you simply are not going to make these objectives.

MR. LEVITT: Thank you. And our final commenter for this part of the session.

MR. MANN: I just wanted to pick up the thread of HACCP through some of the things that we are working with. I have got a sense from some of the comments --

MR. LEVITT: I'm sorry. You need to identify yourself again.

MR. MANN: Oh, I'm sorry. Jim Mann, Health Minder. I get a sense that there are different view of HACCP as terms of what it is. I heard some comments about, well, then we have to break it into HACCP, like way beyond the analysis part. I was ascribed that anybody, whether it is Nancy cooking a hamburger or whoever, we make an assessment of the risk on everything we do, and at the time where it seems like allocating our resources is the biggest single issue that we have.

There is never -- we are never going to reduce the risk to zero. We are never going to have the number of people that we want. What are we going to do? That is what HACCP is. And HACCP is a process to think it through. And it is a method to apply the resources to the risk.

Somebody was saying we wanted a risk assessment all the way from farm to fork. That is what HACCP is. It is a way to think about it. Now it is being implemented in different things. But I would encourage the board to continue that approach because without that approach, it is going to be very difficult to engage industry. They need that help to understand that it is not rocket science. It is not tough, tough, tough. It is not that impossible. It is actually quite simple.

The frustrating part of this, as I would remind you as parents, how frustrating it is. Isn't it tempting to hit them? And that's kind of -- you know, we are not going to be with them all the time. So we teach them. We teach them to defend and learn. And I think the one big factor that comes together here, and it is certainly in the work that I have done with the chains -- they are trying to work so hard to protect their brands, we don't have to worry too much about them in terms of doing other things. If we could figure out how to help them, we would go a long way. And they want to stay in business, and that gives us some continuity. Thank you.

MR. LEVITT: Okay. Thank you very much, and thank everybody here. This will conclude this part of the session. You have sat for a long time this afternoon. You are entitled to a break. We would like to ask you to come back at five minutes to 4:00 for the last session of the afternoon focusing on risk communication. Thank you.

(Recess)

DR. WOTEKI: Those with endurance who are still here, we would like to get started.

(Pause)

MS. WILCOX: Okay. It looks to me like we are about ready to begin again. And we are at our last, but certainly not least, goal on risk communication. I'd like to follow the same procedure that we followed before in terms of looking at the four questions that were asked for goal discussion, what additional objectives or specific action steps would improve the plan, what issue or concern would these address, what objectives and action items should be given priority and why, what is your expectation of success, and how do we measure the success of the plan, especially this particular item. And then are these organizational statutory or other changes that you suggest we consider in achieving the goal.

I think I'll just follow the same format and ask the table on my right if there are people who would like to comment, and then we'll just move around the room. Sir.

MR. SAUNDERS: This is actually more of a question.

MS. WILCOX: Could you give your name, please?

MR. SAUNDERS: Yes, I'm sorry. Doug Saunders, with the Virginia Department of Agriculture, and also the Association of Food and Drug Officials. This is actually a question, just a point of clarification, if you will. There have been mentions of certain issues today. And I just wanted some clarification as to whether or not this document was intended to cover these particular issues in any way, shape, or form.

Joe, you had mentioned earlier that you had purposely drawn the line at dietary supplements during previous deliberations. And there have been mentions of

GMOs or genetically modified organisms, and also bioterrorism in foods. And I can see where those things can fit into this plan in some way, shape, or form. But I was wondering if this preliminary plan was intended to cover those particular issues specifically.

MS. WILCOX: Let me try to take that first. I would say that the plan is intended to cover any food safety problems that might emerge. And some of the things you mentioned could be considered food safety problems, and others might not. If they were then -- if those categories or other categories emerged, I would hope that the plan would have the capacity to help us to manage those risks just like any other.

MR. LEVITT: I mean, I agree in general with what Caren said. Sometimes as you go through time, you know, new things kind of creep in that you haven't thought of before and try to figure will they fit under the same framework. Bioterrorism, I would say, is a good example of that. Was it part of what we thought of as we were doing it? Probably not. Do a lot of the issues there fit under here in some logical way? The answer is probably yes. And so part of it, as you go through, you can help us, you know, fine tune what you think the scope ought to be.

On biotechnology, which was the other area that you mentioned, you know, we would consider this plan covering all products regardless of their method of production in terms of food safety. I would clarify a point that was made earlier by one of the speakers in the last session about allergens in biotech products. There is action -- there is testing that is done to identify whether there are any known allergens. And if

there are, they are required to be listed in the products.

So, I mean, that is something that existing systems already take care of. So I would say the areas you mentioned are areas that are kind of hovering around there. They were not central to what we were thinking about when we drew them up, but you ought to help us fine tune in terms of what, you know, the scope at this point ought to be.

MS. WILCOX: Okay. Stacey?

MS. ZAWEL: Thanks, Caren. I just had a few --

MS. WILCOX: You want to -- for the record.

MS. ZAWEL: Oh, I'm sorry. Stacey Zawel, with Grocery Manufacturers of America. I had a few comments on the communications goal, and then one general comment. So let me just start at the beginning with the goal itself. At the end of that or somewhere in there, what I would suggest is that we lay out explicitly who the goal is for. And that is, my suggestion would be that the United States food safety system openly and effectively provides information on food safety risks and education, on how to control those risks to industry, consumers, the medical community, and educators, and others.

And then under objective one, I would add the word "accurate" in the following manner: "Sustain public confidence through effective, open, transparent, accurate, and timely information." I wonder about the word "exchange" there. My instinct would be to take it out because it suggests that there is kind of an ongoing dialogue between the government and the public on a food safety issue, and my understanding of the objective -- and maybe that is where my understanding is wrong, and

maybe you could clarify -- but that that is -- the intention is to provide the public with information so that it would essentially be one way and not necessarily an exchange.

MS. WILCOX: I think that there are certainly occasions when it would be both ways, multiple ways.

MS. ZAWEL: Yeah, I see that. I mean, I think that it is important to have -- communication, I think, is important for industry to be able to communicate with the government, et cetera, on these things. But I wonder -- I just wonder if that is in fact what you are trying to get across because the -- and then I would wonder if that is in fact what we necessarily want to do with respect to communication.

I think that what needs to be done in terms of our communication goals on the plan or the federal government -- the national -- the federal government and the national plan as well is to have a system in which communication activities and goals are set up and communicated outwards, and that everybody along the continuum, if it is the industry, if it is educators, that we are all achieving the same goal to someone and maybe not necessarily affecting an exchange, even though an exchange is important.

And I don't want to belabor the word itself. But I just would note that.

MR. LEVITT: No. I think it is a good -- I mean, sometimes we try to get multiple thoughts, see how many multiple thoughts we can squeeze into one sentence.

(Laughter)

MR. LEVITT: There is a probably way to say it. And I think you point that out, you know. There are a lot of different subpoints within that one sentence.

MS. ZAWEL: Right.

MR. LEVITT: And you are trying to tease them apart.

MS. ZAWEL: Well, yeah. I am trying to tease them apart so that when somebody reads this, we all know exactly what it means and that we don't have to necessarily interpret it. That's all. And then --

MS. WILCOX: Let me follow up with that. Would you -- could you see another objective that would talk about the times when there would be an exchange, where communication would be an exchange?

MS. ZAWEL: Absolutely. I think especially with respect to talking about outbreaks and what is happening with outbreaks as they unfold. I think it is absolutely essential and would, you know, have discussed this previously when I represented the fresh fruit and vegetable industry, and we talked about it a lot under the context of force G and how can you enable a system, the government system, to accommodate the industry and others.

And, you know, we had -- there was a real challenge in trying to set that up because a lot of it is proprietary and, you know, I wouldn't disagree that it is not for a good reason. But in those instances, I think that there are opportunities for exchange because there is a lot where the industry can help the government, the government can help the industry understand what is going on. And so those exchanges, I think, are important and maybe should be explicitly stated.

Can I go on? With respect to the second -- actually, I just would like to

make one general comment about all of the communication. In objective No. 2, the medical care providers are noted. I would like to emphasize that the medical care community needs to be engaged in just about every action item, and certainly in every objective. I think it is extremely important that they become one of the focuses. And so under the second action item, I would -- which is kind of -- the way that I would interpret is that it is focused on food safety communicators needing the media.

But I would actually include medical doctors and others knowledgeable, and would state something like this, "Knowledgeable communicators such as journalists and reports and medical doctors," et cetera, et cetera, et cetera. There are a lot of -- under communicators, I would just use that word much more broadly because I think that our challenge here is to communicate food safety risk. I think, you know, everybody in the room understands that.

And with respect to implementing such an action item, I would suggest adopting a teach the teacher type of program because I think that given the resources -- I mean, you know, if you -- I question what resources we are going to have to carry out the entire plan. But that is one way that we can use, effectively use, the resources that we have and really get a broad network out so that we can implement change.

And let me move down to the third action item. I would again add the specific communities that are targeted there, where it says, "Establish opportunities for public/private partnerships to promote effective transparent communication about food safety risk, prevention strategies, and enforcement actions to consumers, vulnerable

populations, and medical care providers, et cetera," to lay out exactly what is meant there.

And I would like to emphasize throughout this as well that, you know, I think we have all heard Mr. Levitt's analogy of the boulders, which I think is a very good one and a very effective one. But if we are trying to get change in behavior, we need to start where we can make the biggest bang for the buck. And I think that targeting communication messages to vulnerable populations is one of the first places that we need to go. And doing that, I think we can be most effective by going to the medical community.

It is a very large community, but nevertheless it is a targeted community, and something that is desperately, desperately needed. And as an example of that, when I was pregnant very recently, I asked my obstetrician if I should be concerned about listeria. And she said, oh, no, that's not a concern for pregnant women. And, you know, there are many, many stories that are synonymous with that that go even beyond that to suggesting that listeria is a sexually transmitted disease.

(Laughter)

MS. ZAWEL: So, you know, this is -- there is desperate need for education. And I think we can make a big impact. And under that, under that action item, as a subset of that, I think that one of the steps could be to in fact develop some -- like a committee of sorts where the government -- I know that you guys have relationships with the American Medical Association and things like that. But I don't know if there is a structured organization or committee or what. But I think that something like that could

be developed in which you could get to a lot of the affected population.

Let me just go right before the last action item of objective two, where it says, "Evaluate university curricula related to food safety fields." I would add medical schools as well as a target in there.

And then moving down to objective three, include -- like I said before, I would just like to emphasize that we need to include vulnerable populations in our outreach efforts. Then in action item one, "Establish active research outreach strategies to provide rapid public access to accurate information about food safety emergencies." I know I am belaboring that point to make a point, but I think it is very important that not only do we expedite the release of information, but we also try to assure that it is the best information that we can share to get action on behalf of the public.

And finally, I'd like to just make a general overriding comment that kind of has to do with risk management and risk communication in that. I know a lot of times in this town much of what we do is solely political, even though I believe in my heart that we are actually trying to do something important, and we can actually affect change in a positive manner. And this exercise could certainly be seen as extremely political, seeing as it is so big, and somebody mentioned a change in -- you know, we have an election coming up. God only knows what that is going to do to some of these goals. And I certainly hope that regardless of that, some of these are going to ride through that storm.

But the action of USDA last Friday that with respect to publicizing every recall, whether or not it has to do with the health risk, kind of concerns me. And I think it

certainly flies -- is representative of something that seems to be against what the plan lays out and would then suggest that in fact this is solely a political exercise because public policy that is being implemented at this time actually goes against the grain of what is in the plan. Thank you.

MS. CODY: Mildred Cody, from George State University. I am representing the American Dietetic Association. We were really excited to see that the risk communication part stayed as a separate unit. And I just have a few comments. And I really appreciate the comments that you have made because we really will echo quite a few of those.

We would like to see that health professional be included with knowledgeable communicators. And because health professionals are a fairly wide range, we would like to see that they not be necessarily targeted out as physicians or nurses or dieticians because there are a range of professionals out there.

Under the action item that talks about launching a nationwide public information campaign, we would like to see that libraries be included as one of the places that we reach consumers. Libraries are typically low threat. We have both public libraries and academic libraries. And because they are the normal depositories for information, we would like to see that they be included.

We would like to see, though, that the information sent to libraries be a little bit more clearly marked than information sent, for example, to an extension office. When you send something to a library, they may hold onto it for 10 or 15 years, just

because it is holding a place on the shelf where they might consider it to have historical value. So when there is an update for something, we would like to see it marked, you know, this updates so and so, remove it and discard because we want to see that the best, most current, most accurate information is available to consumers who are using the libraries.

We would also like to see in this nationwide public information campaign, whether it is Fight Back or some kind of derivation of that campaign, that it go beyond very general recommendations. For example, it is difficult to know what "chill" means. You know, when my 17 year old tells me to chill, I don't think it is quite the same thing as we mean. But beyond that, it is very difficult for a consumer to actually know what to do. We don't have, for example, refrigerators with thermometers.

If you have looked at your refrigerator lately, it has a cute little dial that you can turn either way, and it doesn't mean anything. What you do essentially is if you have got it too cold, your lettuce is freezing, for example, and you turn it back up just a little bit so that your lettuce won't freeze. That is not quite the same thing that we would like to see.

And, for example, I know nothing about cars, don't want to. But I can tell you that when I get in my car, there is a little red light that comes on if something is wrong. And I do know where to go to have that checked. Nowhere in our food safety system do we have that. It is not consumer friendly.

Under objective two, we were really excited to see the potential for online

distance learning courses, especially for professionals. We feel that we don't want to see every professional in the country converge on their local university. We want those professionals to stay scattered. We want them in rural areas. We want them in areas that are hard to reach and access. We don't want them to all be in one place at one time. That is expensive, and it really is not functional in terms of lifelong learning. So we were very excited to see the online distance learning courses and to see that there is language here on attempting to make them interactive, both in terms of activities and in terms of being able to actually communicate with another individual to answer questions.

We were again excited to see the opportunities for science teachers. But we would encourage you to look at K through 12 curricula, perhaps in dialogue with the Department of Education. I'm not aware of any state in the country that has as a standard of education any food safety standard. And without a food safety standard, it is unlikely to become a part of the curriculum in any class except for a class that has a very interested teacher.

In addition, having an interested teacher does not necessarily give you good use of the curriculum. You may have a teacher who has a bias in one direction or another and simply gives their opinion. We need real curricula. And if they are going to be effective, they need to be institutionalized as a part of the standards.

Again, under objective three, we would like to see the medical community included, especially for vulnerable populations. And we would like to see some specific wording that directs training for health care professionals who work with vulnerable

populations because we think that those individuals have some very specific and personal food safety needs, and we want to be sure that they are getting the appropriate information, not that listeria is a sexually transmitted disease.

Thank you very much for your time.

MS. WILCOX: Okay. Anybody else on this side of the table? Go to the end. Ms. Tucker Foreman.

MS. FOREMAN: Hi. Carol Tucker Foreman, Consumer Federation of America. And I apologize that I haven't been able to be here for most of the day today. I have spent a fair amount of time going over the draft preliminary food safety strategic plan over a period of time. And I was trying to remember. I think you have been working on this since 1997. Is that correct, that is going on then three years?

MS. WILCOX: The President's initiative has been underway that long, yes.

MS. FOREMAN: I think there is a lot of good material here. But there is one very serious -- there are two very serious problems. And I think one is the cause of the other. The difference between platitude and plan is specific commitments and time tables to accomplish the goals. This is a plan that has a lot of goals on it. I have a lot of goals in my life. I get up every morning with this list of things to do. And they are never accomplished by the end of the day unless there is a specific time allocated to accomplishing the goal.

I don't understand a strategic plan that has not one date or specific time

table in it. You are going to upgrade, you are going to expand, you are going to improve. But on none of the action items does it say this will begin at this point, and we expect to have it half way finished by this point and completed by this point. Without those things, I think this is platitudes. It is a meaningless document.

Nor does it specify any place that I can find what kinds of funds it is anticipated will be needed over each year that you are going through this process and how you will go about getting those funds.

I think the reason that those things aren't here yet is because although this is supposed to be a unified plan, what you really have still is three agencies and four entities working to make sure that each protects its own jurisdictional bailiwick here. There is no unified budget process here. God knows there is no unified time table setting here. And as an informed observer goes through this, what you see is that it appears there has been a process of making sure that each agency maintains each of its action -- each of its bailiwicks of jurisdiction now. And there are no real specifics about how you are going to bridge those.

This is a document that assures that you will continue to have an FDA center for food safety and applied nutrition and a USDA food safety and inspection service. And there is really no unity of purpose in this document. And, frankly, I don't see that it is possible until you begin to address that problem.

The other issue that I would like to comment on here -- and I'm sorry, I'm searching for the right words for it. It is the fact that this process has been going on, and

the words don't get very much more specific than they were at the very beginning of the process. Three years have gone by, and you are still repeating the same generalities. There are specific gaps.

We know, The Washington Post told us last Sunday, what a problem we have with listeria. I don't see anything in here that addresses the specifics of listeria. You say you are going to determine what are the priorities with regard to determining what the greatest risks are. Gee, I think that by now we would have been through some of that process.

The United States government file cabinets are full of documents like this that have never gone any further than this one toward accomplishing their goal. And I think that this one is probably going to be still born at this point, too, unless there is somebody who gets the two agencies into a room and says -- the three agencies, and says, this is what you need to have to have a plan. And you have to stop protecting your own little backyards and work together in order to achieve these goals, or they are not going to be achieved.

I'm really disappointed that after all of this time working on this, there is nothing more specific here than what it is here now. It is a document that in the -- you know, the executive summary goes through and states three or four points. And then those are restated and elaborated on through the document instead of saying this is what we are going to do, and this is the date we will start, the date we expect to be partially finished, and the date that we expect to be completed, and this is where we are going to

get the money to do it. Thank you.

MS. WILCOX: Thank you.

MS. DUNHAM: Bernadette Dunham, with the American Veterinary Medical Association. Just a very small comment. It sort of goes along with the first comment we heard about the groups that you are addressing when it comes to involving education and training. When you allude to the first paragraph of risk communication, you are involving everyone in a global farm to table chain. And there is a list that we need to be informed with.

When you come over to the specifics of objective two, and then you are listing a couple of the groups, growers, producers, transporters, retailers, consumers, regulators, public health workers, medical care providers, whether or not for consideration of highlighting more names is something to go for, sometimes people react when they see their categories listed.

And in here, you also have the opportunity for the food handlers, the extension specialists, which we can utilize. And they have marvelous programs already set up right now at the universities to use to assist in reaching out on these programs for the action items that you have listed. And the veterinarians and your agricultural educators, specifically, they may not be necessarily the producers, but they are also involved with that. And they are a great resource to add.

So without going into a long list of every aspect, but ways in which you can earmark that so people sort of say, oh, yeah, I am involved in this. Thanks.

MS. FINELLI: Mary Finelli, concerned citizen. I haven't had a chance to do much more than scan the document. But I haven't found any provision for new laws or updating current regulations. And again, my concern is with the unrealisticness of voluntary measures, especially at the production stage. And objective five in particular concerns me, the use of the word "established." It reads, "Protect the food supply through consistent training and consistent enforcement of food safety laws and established regulatory requirements." I don't really see the need for the word "established" in there, and it concerns me that it might preclude new regulations.

And I have a question on objective two, just how standards are defined. Is that something mandatory, or what is a standard defined as?

MR. LEVITT: Part of it is that you want to tell us where you think -- you think it ought to apply to mandatory standards?

MS. FINELLI: I think somewhere we need to have some provision for updating old regulations or implementing new ones. And I'm not seeing that here. And I'm thinking that might be a place to do it, and also to include the production stage, something along the lines of -- and again, this is objective two under risk management goals -- "Promote development and implementation of preventive practices, techniques, and controls using risk based approaches and -- " I'm sorry " -- and the establishment of national regulatory or mandatory standards, including performance standards where appropriate," something along that line.

And another comment I have is I think something that is missing -- and

again, I haven't had a chance to really review the document thoroughly. But I think that trace back, I haven't seen trace back mentioned. And I think an effective trace back system would cause industry to begin to discover solutions to their production problems overnight.

And a final comment is I have been attending these meetings consistently. I don't think I have missed a one for the last few years. And myself and others have pushed for prevention. And it is mentioned as a guiding theme in this document, but I would think if this is supposed to be a prevention based system, it would be at the very least the primary theme. And I see it continually playing less and less of a role in the plan. And that is extremely frustrating and discouraging. Thank you.

MS. WILCOX: Thank you. Yes.

MS. KELLY: Karlease Kelly, with the FSIS technical service center in Omaha, Nebraska. My comments relate to the risk communication goal. With regard to objective one, we talk about sustaining public confidence through effective, open, transparent, and timely information, maybe or maybe not exchange, regarding food safety risk, prevention strategies, and decision making.

It seems to me that there is an important component that is missing in that statement, and that is the component of implementation, be it implementation of regulatory changes or implementation of some of the things that people will suggest in terms of best practices. But information -- I'm thinking of information exchange in terms of what is working, what is not working, how people are doing things. That can be very

powerful. And I would like to see that added to the objective.

And in that regard, I would think that you might want to add an action item that relates to that, such as provide access to information regarding the implementation of regulatory changes and/or best practices, something in that regard.

Also, in relation to objective one, the first action item talks about creating a state of the art national information network, which is an intriguing idea, but when I read it, it seems to be very vague, and I'm not really sure what it means, such as what is included. I have a lot of questions when I read that, what is included, who is involved, how is information shared, et cetera. And I just wanted to put on the table a concept that has surfaced. I know that it has been articulated by Joe Corby (phonetic) with the state of New York. And it has also been articulated by Dr. Paul Thompson, who is director of technical service center. And that is the establishment of something called or something like a national center for information and education, food safety information and education.

I think that the concept itself created some anxiety because people wonder, you know, is that going to be in a particular agency, you know, is that going to be in a particular location. And I think that maybe those questions could be answered as you work through that. And maybe it doesn't have to be in -- I think it needs to be something -- as this action item states, it would be something that coordinates information across agencies as they currently exist, that it may involve multiple locations because there are, as we talked about this morning, a number of people who could contribute to that concept.

And my final comment relates to objective two. It talks about developing state of the art science based education and training program for -- and then it lists a number of important constituents and groups that are involved in promoting food safety.

Just as we talked about this morning, I think that there are a number of people and groups out there already involved in providing education and training programs. And so what I would like to suggest is that as the first action item, we add something that is not there, and that would be develop an inventory of the training and education programs that are currently being provided because I think just having that information available, even names, addresses, phone numbers, and general topics of things that are being provided out there, could be very helpful. And people who are currently providing programs might be able to access and have information exchange among themselves in that regard. Thank you.

MS. WILCOX: Thank you. Are there other comments on this side? Oh, let me go with her standing there. Go ahead.

MS. SOSA: Meryl Sosa, on behalf of Food Animal Concerns Trust. FACT believes that the list of goals and action items listed in this document are meaningless without a decision on what type of organizational structure will be established for the new food safety system. FACT believes that the recommendation by the committee of the National Research Council to ensure safe food from production to consumer that an independent, safe, single agency at the cabinet level would be the most effective method for ensuring the safe food of the United States.

A person who would be a member of the President's cabinet should have both legal authority and budgetary control for food safety. Without -- a single food safety budget would make it clear to the public whether the government is placing sufficient emphasis on the issue of food safety.

In reviewing the draft plan, there are numerous examples of statements made by the council that show why a single food safety agency would make more sense than simply trying to make the current system work. For example, it says the differing approaches to determining food safety and who bears the burden of what determination -- of that determination under the various statutes just leads to more confusion. And if we had a single food safety agency, we wouldn't need to have different approaches and different burdens and that sort of thing. Everyone would be operating under the same system.

So when you look at the options listed at the end of the document, we don't see how any options other than options listed under Roman numeral V would solve any of the problems existing in the current food safety system. And in fact, none of the other options were supported by any kind of information. Moreover, no option, other than Roman numeral V, would address the conflict of interest issue posed by the current food safety system. In the current system, the regulatory agencies entrusted with different aspects of food safety often have dual purposes that may stand in opposition to each other, diminishing agency effectiveness in addressing food safety.

For example, the USDA addresses food safety under the double mandate to

both regulate portions of the food industry and promote its products. The juxtaposition of these two purposes within one agency conceivably places the interest of the food industry over and against the food safety needs of consumers.

In the FDA, part of the purpose of the FDA Center for Veterinary Medicine is the consideration and approval of animal drugs and their uses. Yet the Animal Drug Availability Act increased the role of industry in the FDA's new animal drug decision making process. In effect, the FDA now is called upon to respond to the interests of food safety and the animal drug industry.

One of the other areas where this dual purpose may threaten food safety is in the FDA's oversight of the antibiotic approval and use. The more frequent the use of the antibiotics, the greater the pressure for selection of antibiotic resistant bacteria, and the greater potential that this resistance will pass through the food chain to consumers. But this reliance may put the well-being of the consumer at risk. Hence, the FDA is increasingly pulled in two directions.

The final example of this conflict of interest was evidence by the recently released document called, "The FDA Response to Comments on a Proposed Framework for Evaluating and Assuring the Human Food Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food Producing Animals." I'll just call it the FDA response.

For example, the FDA response states that norms would be inadequate to assess the safety of specific food antimicrobials after approval. And it goes on to a very

lengthy analysis of why norms would be inadequate. And yet, despite this lengthy analysis of why it would be inappropriate, FDA concludes that due to the number of comments objecting to the studies, FDA has decided not to propose that on farm monitoring be a post-approval requirement, and instead rely on the norms program to track loss of susceptibility or development of resistance.

Other than this statement, no one else is supporting this decision -- was provided in the FDA response. Since pharmaceutical companies would be the parties responsible for performing post-approval studies, one can only conclude that it was their comments that persuaded FDA to eliminate this post-approval monitoring requirement. And I would like to add as a side note that we perceive that that is an extremely important requirement in determining the issue of antibiotic resistance and what is happening with that issue.

Finally, the new single food safety agency should be empowered with regulatory authority as well as enforcement powers. The current food safety system does not confer sufficient enforcement powers upon the agencies entrusted with the authority to regulate food safety. For example, the FDA can conduct trace back investigations where food borne illness outbreak has occurred. But the FDA does not have authority to force the company to recall the products that cause the outbreak.

The USDA can adopt regulations that require companies to comply with HACCP, but the USDA cannot force a company to recall contaminated or adulterated products, even if they occur as a result of HACCP violations. And I think the recent

example, as I discussed earlier with Supreme Beef Processors, is very illustrative of the problem that the regulatory agencies are now facing because industry is openly contesting their authority to do what they need to do under these new regulations. And so if the agencies -- if the new agency is empowered, then it can act in the consumer's interest to protect consumers much better than trying to somehow jerry rig the existing statutory structure to fit the needs of the current -- the current food safety needs of consumers.

I would like to add one other thing. The experience of four countries in consolidating their food safety systems is really helpful. And I think we need to look at the GAO report that came out, I think in May of 1999, which looked at the different food safety systems of four countries that are now establishing a single food safety authority, and why they are doing that, and why they feel that it is going to work for them. And they recognize that there are going to be short-term costs, and those may be substantial. But they feel that in the long-term, there is going to be significant benefits in terms of money saved, more food safety for the money spent, and/or better assurance of food safety.

And the GAO stated that officials from these countries believe that consolidating food safety activities would, 1) improve service delivery by providing a single contact for consumer and industry clients; reduce overlap and duplication of services; improve or reduce the need to coordinate food safety activities, thereby enhancing the efficiency and effectiveness of food safety regulation; provide more effectiveness of food safety regulation; provide more comprehensive oversight of food safety from farm to table; and enhance food safety, thereby providing continued access to

international markets for producers and processors. And all of these concerns are definitely of concern to us.

At FACT, we have said only a single food safety agency headed by a cabinet level official can adequately address the food safety issues presented in the new millennium. Further, simply tinkering with the more than 35 federal statutes that currently regulate food safety will do nothing to create a cohesive and comprehensive food safety system. Rather, new updated statutes and regulations that adequately address modern food safety issues and that will be flexible enough to adapt to the ever increasing issues posed in this area must be adopted and implemented.

FACT seeks a meaningful dialogue on this issue such that the input provided by consumer groups as well as other groups is considered. Thank you.

MS. WILCOX: Thank you.

MR. EMERLING: Stan Emerling, North American Meat Processors Association. I would just like to go back and refer to what Mr. Cody said about the Department of Education and having those programs from K to 12. I think that one of the things that is overlooked in this communication segment is that we would be better off starting at younger ages.

All that I see here is designed at the professional level or midlife crisis level, whatever you want to put it. And if we can teach young people about safety, like their old home economics courses used to do. And I understand some schools have now restarted that. But for the most part, those programs have been gone. In the beginning, they were

mostly focused, I think, at young ladies. We ought to make sure that the incorporate young men as well.

There was a thing in The Washington Post today about handwashing again on the business pages. I think we need to take a look at that and then go forward and have classes in medical schools and dietician programs and other places that would be helpful.

In a general sense, what I hear is this initiative getting bigger and bigger and really more complex. Maybe you ought to take a look at prioritizing what really needs to be done first out of all of these things that you have laid on the table, which are some excellent suggestions. But it is massive, and it may not get done, as Carol Foreman said and I said earlier.

Why don't we try to take a look at what will provide the greatest food safety impact out of these things and try to move forward in a positive, quick fashion so that we can show we have accomplished something and so that it doesn't end up in a bottom drawer in somebody's office. Thank you.

MS. WILCOX: Thank you.

MS. BILLAUER: Barbara Billauer, Association of Environmental Health Academic Programs. Before I address objective two, which talks about the training, I would like to make a comment. Actually, my colleague from Minnesota --

FEMALE SPEAKER: Georgia.

MS. BILLAUER: Georgia -- sparked something that I think maybe

crystallizes all of this. I am not equipped or qualified to say whether 1 agency, 4 agencies, 25 agencies are better addressed to handle an all-encompassing problem that addresses every issue of American life, from behavioral changes, as you mentioned, to industry, to agriculture. Maybe you need a managing expert, many you need Tony Robbins, I don't know.

But I'm here to listen to some of the public health aspects of the approach. Should we be focusing on food safety, or should we be focusing on preventing disease as a consequence of food and water borne exposures? And the difference is slightly different. I don't really think that John Snow (phonetic) really cared what caused cholera. But he stopped it. And your comment sparked something. We don't have thermometers in refrigerators. Why not?

We have little labels on my air conditioner that tells me how many British thermal units I use. I can't buy a device without knowing how much energy consumption. I can't eat a candy bar any more without being confronted by how many calories I am going to eat. I can't buy a car without seat belts. And indeed, if I don't use my seat belt, I can be fined. And when these risks address large groups of people, greater safeguards are implemented. A plane cannot take off without everyone wearing a seat belt.

So we are talking about statutes. Why don't we have a statute that says that refrigerators cannot be made without thermometers? Why don't we have a statute that says for large institutions that serve public groups that are large groups, that the thermometer is tied into a surveillance network. If it goes below a certain temperature --

my thermometer at home, if the heat goes below a certain amount -- it goes into the food company. Why don't we do things like that?

These are things that don't address major identity issues as to who is doing what, which maybe you need to address. I'm not minimizing that. But I am saying these are forward thinking ideas that tack onto what can we do to promote public health. By the time our cook friends get to cooking that food, it is probably too late. In many cases, it is definitely too late for certain microbes that produce certain toxins.

We need to identify the problems -- and we have so many epidemiologists here -- of where we can stop the problems from fish and farm to fork, that we can do without changing the structure, separately apart from looking at the structure.

Getting down to the education of professional or younger people, there are some wonderful ideas in each of the sections. The idea of monitoring professional curricula is in the risk communications. There are different ideas in each section. And I almost got the sense that each section was written in a vacuum. There are some ideas in risk assessment that I wish were in risk communication, and some ideas in risk communication that I wish were in risk assessment and management.

Education in and of itself needs to be treated as one entity. What focus -- what is the strategic plan for education? How will we educate the food professionals, the environmental professionals of the future? Will we teach them the public health perspective? We will teach them organizational management? Which one gets priority? Who is going to decide what is going to be in that curriculum? And some of these ideas

are wonderful. Live discussions with experts. But who is going to decide who the experts are? Who is going to fund them?

And then we get down to the specifics of communication. And I have read more than I would like to about communication and risk communication. The single most difficult -- there are two difficult issues in risk communications. And I actually sat in on the Brook Haven community meeting when they told the 600 or so constituents that their drinking water was contaminated with radiation and BOCs and a whole bunch of things. And the poor medical officer couldn't speak English. I mean, he was not American. Forget about speaking in lay terms.

So there needs to be a way to communicate not complicated information necessarily, but I think George Bernard Shaw said that every profession creates their own language so nobody else understands it. There needs to be a way to translate information so that the consumers can understand it and make decisions for themselves rather than listening to the loudest voice.

And then there needs to be -- and this I really don't see too much of this in communication books. But there is a tremendous amount of psychology that goes involved in hazard and risk communication because for the most part, you are not telling good news. And when people are confronted with bad news, they do one of two things. They shut off or they overreact. And maybe grief counselors or linguistics experts need to be recruited into the process of conveying the information so we don't have California Proposition 65 with information overload and everybody is tuning out, and yet people are

empowered to be able to address these things.

But the issue of education for the task force to say we are going to monitor curricula is a wonderful, noble idea. But is this task force the best equipped to do it? Or is this a prime example of an area where the task force needs to broker a partnership with several organizations, linguistic psychologists, because there is a tremendous amount of cognitive dissonance which goes on. And you see it even in this room.

People don't hear that which doesn't fit within their preconceived notions of what they believe. And the idea is we are going to have to communicate things that maybe are not the most pleasant to hear in a way that people still have the energy and the power to do something about it. And I think that is part of the problem we are facing here.

We need to be able to put forward this information in a positive way so we are not looking about destroying organizations, pulling them apart, attacking, but we are moving together in a positive way to go forward and prevent disease. Thank you.

MR. LEVITT: Thank you. Caren Wilcox got called away for something directly work related, I'm told. So I will just pick up and continue the discussion. I think with the last group, I'll run around this way. And these people, this poor table got called upon last. So we'll switch it around and let us start first here for people to please come up to the mike.

MR. MANN: Jim Mann, Health Minder. Unfortunately, I am going to stick with a fairly nebulous point rather than tying it to a particular action here. One of the

things that -- and as I sit here and decide how many times I represented in the room, I see a lot of regulatory people here. And I guess if I had a show of hands, I would probably the outnumbering part. And I feel very represented by them as a consumer.

And then there are consumer groups here that represent me as well. And there certainly are a lot of differences here in opinion on what I want as a consumer. And what I like, what I see here, is what I really like is the vision statement, particularly the beginning of it, the process that we are all trying to make it better. Nobody has an answer to whether this is a -- what we want to do should drive the organization. It shouldn't be the other way around. We have to decide what we want, then decide what organization it takes.

So I just want to thank the group for inviting us here. I appreciate the opportunity.

MR. LEVITT: Okay. Thank you. Anybody else over here? Yes, please.

MR. WHITNEY: I would like to address what I see as an omission from objectives one and two. We have got several interest groups identified here in terms of communication. One that is completely overlooked are culinary professionals and culinary educators. I would be curious to know how many of the epidemiologists, how many of the regulators, get calls every Thanksgiving and Christmas on how to cook a turkey, on how to cook a prime rib.

If you are trying to get credibility for sanitation, aspiring cooks and chefs typically go through some type of vocational training, either at a cooking school,

vocational education center. These are the people who are controlling much of the food and much of the sanitary practices that are going out, either directly in their own kitchens or by talking to their friends and neighbors. If you overlook that group, you overlook your tremendous opportunity to influence public opinion.

Related to that, in objective one, I would strongly urge you to keep the idea of information exchange rather than one way communication. To eliminate exchange, I think you squander an opportunity to assess how effectively you are communicating your message because an exchange not only identifies misinterpretations and miscommunication as information is exchanged back and forth, it also overlooks the idea that people can question does that apply to me, does that apply to this particular circumstance. One way communication gives you no feedback loop as to how effectively you are getting your message out and whether you are reaching the right populations.

On that same note, one way communication, in my experience, always has a credibility problem. If you enable people to question what is being communicated and answer that and elaborate on the original communication, I think you'll greatly enhance your effectiveness.

MR. LEVITT: Before you step down, could you identify yourself again for the record?

MR. WHITNEY: Joe Whitney, the Whitney Group.

MR. LEVITT: Thank you. Anybody else from over here? Going around the outside of the room? Anybody in the back? Anybody across coming around this side?

We are getting closer to 5 o'clock. Yes, please, Stu.

MR. RICHARDSON: Comments about maybe next steps a little bit. You know, we often time look at the progress we make on issues, and then we become somewhat satisfied that we have not progressed very far. That is natural, and it is very healthy. I mean, but I submit we have done -- we have made some progress. The last year, in this -- not this building, but in a building downtown here, was the first time Health and Ag folks first met together to talk about issues.

Granted, the food safety initiative has been going on for the last three years, and granted that there is an impatience to accomplish more. But we have had dialogue, process, products, and activity that we would not have otherwise had.

The council, the task force, must be commended for their energy to seek our input, not only inviting us here today. But you went out to the states. You had grassroots screenings. You were very open to take the criticism and the barbs that we had about how things were broken, how come you haven't fixed them yet.

But what is needed now is next steps. A lot of good has come out of this process. But being from California, being so far from Washington, we wonder whether this document maybe hidden somewhere here, and we'll never find it in California as well.

The survivability of this activity is essential to us. It is a long time coming. It is essential that it move past this administration, it move with time frames, it move with action steps that are clearly quantified, and it move with an organizational commitment at the federal level, and I submit an external element of federal, state, and local officials and

others working to implement the action steps.

Without these elements and ingredients, not only will we wring our hands, but we are going to be very satisfied with ourselves, consumers will be even more critical of us than they already are, and I think really the most important thing, we have failed what our jobs are to do, and that is to provide consumer protection and the utmost of public health practice in the United States.

We can take these ideas, and if we don't take them in a way that -- we can take these concepts of risk management and risk assessment, risk based information, and do those kind of analytical processes. They make sense. But if you do not have a system in place which takes those very low priority items and says we are not going to do that because over here somewhere else is more important, and we are going to move resources over there, and I have the power to do that, not only at the federal level, but at the state and local level, then we will fail in our ability to do the consumer protection kinds of chores we are charged with.

Thank you very much.

MR. LEVITT: Thank you. And maybe we can use that as an segue into our final session. But first let me ask, are there any comments specifically on the third section on risk communication? Yes.

MR. WEATHERMAN: My name is Greg Weatherman, American Culinary Federation. And I would like to point out that in risk communication management --

MR. LEVITT: Speak a little closer to the mike, please.

MR. WEATHERMAN: An integral part of this risk communication is the FSTEA group, Food Safety Training Educational Alliance. I think something should be said in there directly in this document. It is an example of how different agencies can come together and agree and get things done. It is also a center point for us all to draw from. And I think it is a wonderful model just to look at. Thank you.

MR. LEVITT: Thank you. Other comments specifically on risk communication, the third part of the draft preliminary plan? Okay. With that, we have about a half an hour, a little less, to try and wrap up. And maybe the best way to do it is to pose a simple question, whereto from here. If people could try and address that in a summary way -- just to give you a sense in going around the room twice, although there are less people here now, it has tended to take us about an hour and a half, and we have about a third of that now to do that.

So if people could kind of formulate their thinking when we get to your turn to try to say your point succinctly, then I think that will help us, both everybody hear what everybody is saying, as well as wrap up the meeting on a -- in a useful way.

So with that, with the question of whereto from here, who would like -- I think Stu Richardson really started off the discussion. So who would like to continue the discussion, starting at the table? Yes.

MR. SOWARDS: Dan Sowards, AFDO. Just to reinforce what Stu said, you are going to need to set up some type of committee, if you want to call it a

committee. You can name it what you want to. But there is going to have to be some mechanism to implement the action items that you are going to come up with. And I think once you firm up your action items, based upon the comments you received today, I think you are on your way.

MR. LEVITT: Thank you. Stacey.

MS. ZAWEL: Prioritize.

MR. LEVITT: Caroline.

MS. DeWAAL: I think it is time to kick it upstairs. I think you can continue work on the strategic plan, continue finalizing your action items. I like the fact that for the first time in this document, the government has actually put down options for consolidating food safety functions. And it is -- I mean, it is a full range of options. A lot of them I don't think are -- would be workable, things like just combining the inspection pieces and leaving the policy making pieces back in the separate agencies.

But particularly in the final grouping, number five, I believe, there are a number of new consolidated stand-alone food safety agencies. There are a number of very serious and good proposals that deserve a lot of consideration. I don't believe this council is the one to make that decision. And it is time for the Clinton administration to appoint an outside expert or group of experts to start looking at the question of how to consolidate food safety functions.

This is about consumer confidence. It is really about making a food safety system that has credibility with the public. We have been working with this patchwork for

decades. You all know how it works. All the trade associations, the state people, everyone is comfortable. They have all got their little niche. But the reality is the hazards are coming to us on products we have never seen before.

We don't know what the hazards are going to look like in the future. We don't know where they are going to come from. And we need a credible system to deal with it, not a patchwork, which is what we have today.

So I think the work that has been done is good. It leaves a lot undone. A lot of questions I still have about this document we'll get in writing. But I think on the key issue of structural change and what is needed, it is time to kick it upstairs and ask the President to appoint an outside management expert to do that analysis because I don't believe that any analysis on that question of structural change coming from a body that has the secretary of HHS, the secretary of Agriculture, the administrator of the EPA, the Commerce secretary -- and all the people have a stake in having the system look exactly the way it does today -- is really going to be credible.

So I would really recommend that the council make that recommendation to the President at this time and not wait until the final elements of the strategic plan are done.

MR. LEVITT: Thank you. Who else would like to try to help summarize on whereto from here? Anybody over on -- yes.

MS. FINELLI: Mary Finelli, concerned citizen. I would like to summarize my concerns, basically, by saying that if the plan is serious, it needs to be truly prevention

based with regulated production practices and an effective trace back system. And I would also like to voice my support for option five, the new consolidated stand alone food safety agency under organizational considerations on page 18 of the document.

I think the confusion, the competition, and the passing of the buck by the different agencies, the nonsensical absence of APHIS representation in this room and in the food safety arena, and the mere token status given to the animal production unit of FSIS are all examples which testify to the problems of food safety responsibilities being divvied up among the different agencies, and the bottom line being that it just isn't working. Thank you.

MR. LEVITT: Thank you. Other summarizing or forward looking comments? Yes.

MS. SOSA: Meryl Sosa, Food Animal Concerns Trust. I would concur with what Caroline stated concerning having an outside management expert look at the situation. But I want to make sure that as we progress towards July, which is when I think the document is due to the President, I would hope that the system maintains a transparency to everyone concerned in the industry, academics, as well as consumer groups, so that we are included within the process.

And one of the things that was not done after the July meeting was that the comments were not -- that were submitted were not posted, and there was no official response made to them. And hopefully, if this document does come out in July as stated, that there will be comments as to why certain things were decided upon and certain things

weren't so that people can understand why a decision was made.

And I think this all goes to the question of just making sure that the system is accountable, that the council is accountable for what it is doing, and so that consumers can feel confident in whatever decision is made. Thank you.

MR. LEVITT: Okay. Thank you. Again looking around to the outside. Yes, please.

MR. MANN: In terms of summary, I see that vision statement. I would advise that you keep it short, the vision. And I would think about adding a mission statement in there that would allow you to talk about the period of the strategic plan. It seems to me that this is a five year chunk. So there are some things that won't be done in five years. That's the vision. There are some things that are going to be done in five years. That's the mission. That might help sort those two things out.

The other thing that I would ask is that you talk about the link to actions so everybody gets more comfortable that there is action there. I see a lot of action there. But I think you were right to stay out of it and stay out of some of those time tables and numbers because that is what a strategic plan is. All those things go in the operational plan.

The other thing I would think about is using the HACCP as a bridge, a bridge to strategically think about this problem, a bridge to put into operation, and a bridge to implement it at the industry end.

The last thing I would suggest is I would stay out of the trap of going

outside to an expert consulting group. I was a consultant for 12 years myself. And I think the knowledge is in the room. And I think we have to find better ways to facilitate bringing it out and putting it into action. Thank you.

MR. LEVITT: Thank you. Yes. I'm sorry. I didn't see you standing over there before.

MR. LERMAN: Dion Lerman, Drexel University. I just wanted to reiterate a couple of things I said earlier. One is that this is a partnership process, and I think that is extremely valuable. The input from a roomful of people like this on these kinds of issues is really important. In maintaining a partnership, I do agree that transparency is critical.

My personal platform, obviously, is that training, particularly of food professionals, receive priority. But I want to thank the committee for having this opportunity for public comment. Thank you.

MR. LEVITT: Okay. Thank you. Carol.

MS. FOREMAN: Thanks. I think it is worth looking at what the stakes are here, 76 million cases of food borne illness every year, 5,000 deaths. That is pretty high public health stakes. I think it suggests a need for urgency of action, specific actions. I think there is another thing at stake. It is the loss, continued loss of confidence in government, which we are told by every poll continues to decline. If the government having told us that we have this problem with food borne illness, spending well over a billion dollars a year to address the problem, continues to not be able to use those funds

effectively -- I think the funds presently available to fund food safety from the federal level are quite adequate. They are very poorly used.

I think that it is the poor use of those funds and this constant inability to get a job done that undermines confidence in government's ability to perform one of its most basic functions, to protect public health. There is another level of confidence that is at issue, and that's confidence in the Clinton administration's having made -- and whether it is able to meet a commitment that it made.

There are nine months, ten months left in this administration. The plan is due in July. The commitment was made in 1997. We're now in the year 2000. The question is when you give a plan to the President, is it going to have those kinds of specifics in it that will say to the public the President of the United States made a commitment to use funds and authorities effectively to address an important public health problem, or did they not do that?

I think that judgment will be made once again largely only if you can assign accountability. I think it is amazing that this strategic plan has come out while the government is so eager to implement HACCP programs. HACCP programs involve assigning responsibility to the industry to produce a safe product. And yet we have a strategic plan here that doesn't assign responsibility for having a good product at the end.

There is a good explanation, I think, of what -- of why and what, what the problem is, why it is a problem, what needs to be done. But there is nothing here on who and when and how to pay for it and what laws need to be changed in order to be able to

pay for it. I think it would be useful before you complete the process that every place that there is an action item and a sentence that begins with the verb like develop additional, expand, produce, assign, assign responsibility, and at the end of each one of those sentences say this particular action item that begins with the verb is going to be completed by this particular staff in this particular agency using these particular funds.

And if it requires a change in the law specifying what the change in the law has to be -- if you get through that, then I think that you will have a plan that says to the public, gee, we are really serious about this. We not only can define the problem, we can tell you how to go about resolving the problem. And we'll tell you the steps that we are going to take over the next year or so to begin addressing the issue. Otherwise, we think we'll be back here again and again and again, year in and year out. And the public's confidence in the ability of the government to provide a basic service will have simply been diminished further.

I don't think that is something any of us want or can afford to do.

MR. LEVITT: Thank you. Dean.

DR. SIENKO: Dean Sienko, Ingham County Health Department. Your question, Joe, where do we go from here -- there are just a few points. I think we need to flush out some of these details. Whether we want to call that a continuation of the strategic plan or an operational plan, nonetheless, I think there are issues that were mentioned already in terms of how are we going to do this financially, what would be the time table to accomplish these goals.

One of the things I wrote as I was reviewing the draft -- I had a lot of good, good -- you know, this is a great idea. But, you know, that begs the question. How are we going to do these things? And I think that raises the issues of finance as well as of where and under what timelines.

I think we need to continue this process. And there was a lot of good discussion today. I was encouraged by a lot of what I read in the draft, as well as the comments I heard. I think we are thinking outside of our box, and I think we are thinking outside of all of our boxes. I think those of us who work in the public sector, we sort of align with certain segments of that sector, and we certainly need to think beyond that and have all the groups that are part of this process.

This is learning. And we can -- if we continue to learn to address this serious problem that estimates say affect one out of three Americans annually. I think you need to think about who then will be your sounding group for the continuation of this process. Others share my concern. For most of us, our lives will be unchanged by the election. I don't know what will happen to this process following the election. But it needs to have carry-over. And perhaps one of the things to do is to build some bipartisan support so that regardless of what happens following the election, there are elements in both political parties that see value in what has happened here, and so that it will continue following our upcoming national election.

And then, finally, I think we need to flush out a little bit more and struggle with this issue of federal versus national. I heard today that this is a national process, a

national strategic plan. And if that is so, then I think we need to continue this dialogue, and that the nonfederal constituents need to be involved in working out the details that are our necessary upcoming steps. The process should continue to be broad and inclusionary.

You had a national audience here today, and I heard a lot of good things. And I hope that you agree that you got a lot out of this meeting today and certainly would continue to get a lot out of meetings with this broad group. Thank you.

MR. LEVITT: Thank you. Other kind of concluding comments? Yes, please.

MR. KAY: Bret Kay, with the National Consumers League. I just wanted to say first, we appreciate that this process is here, you know, and that the President and this administration is taking food safety seriously, which is something that we haven't seen for a long time, and we appreciate that. Unfortunately, I am sort of worried that this plan is -- there are some gaps, and that it is doomed at a certain level because what this plan lacks is a unified, independent food safety agency to implement many of the actions that have been put down here, so that without such an agency, we still have the gaps in inspection, monitoring, and enforcement.

We can't have a system where one agency, you know, is doing continual daily inspections and is going to other countries and, you know, inspecting and ensuring for equivalency there, and another agency is failing to inspect even on a yearly basis, and at worse case is sometimes failing to inspect plants, or only inspecting plants once every ten years. It's just -- it's not a feasible way to do things.

The same holds true for imports in an era now where we are -- you know, over 40 percent of the produce we are eating is being imported into this country. The government has to do better than inspecting only 2 percent of those imports.

So what I feel -- you know, without a unified and independent agency to carry out this unified plan and to put these actions into place in one direction, the plan will fail, and the consumers will remain at risk, and consumer confidence will continue to falter. Thank you.

MR. LEVITT: Failing to see any other hands, looking again, I'll just -- Cliff, do you have anything you want to add?

MR. GABRIEL: No. I know an awful lots been said, but I certainly appreciate the comments, and I personally got a lot out of it. And I think that the task force got a lot of good take-home messages. And the real trick is going to be in developing -- well, certainly, continuing to fine tune what we have here, but also tying to it an implementation plan that gets to the issues of organization, of legislative changes, of financing, et cetera. So there is an awful lot of work that we have before us, and certainly the comments that we have heard today will certainly push us, I think, pretty hard in the right direction. So I appreciate that. Thank you.

MS. NELSON: No. The only thing I'd say -- maybe this isn't on. The only I'd say for EPA is that this has just been immensely useful, and I want to thank everybody for coming and for sticking it out through the day.

MS. WILCOX: And I will simply add my thanks for everybody's

participation, and also remind you that the docket will remain open until the 14th, and we really will look forward to reading those comments. And I can assure you that we will. So we will look forward to your formal delivery of those, too. Thank you.

MR. LEVITT: Thank you. And let me echo all of that. A lot of times at the end of the day you are kind of so tired you are not quite sure exactly where you left off. But somebody before talked about in different ways the word exchange. And I think this process is helping us exchange a lot of important views. I think, you know, certainly we come away with on the one hand a lot of reinforcing for a lot of the directions that have been set out in the plan, likewise, a lot of challenging to us in a number of different directions on exactly how to take this to the next level. And we will take those comments back as well as the written comments.

But again, let me echo to thank you, all the people here, who have all come in good faith. I'd almost like to give a round of applause to all of the participants.

(Applause)

MR. LEVITT: Thank you. That concludes the day.

(Whereupon, at 5:24 p.m., the public meeting was adjourned.)

//

//

//

//

//

CERTIFICATE OF REPORTER, TRANSCRIBER AND PROOFREADER

President's Council on Food Safety
Name of Hearing or Event

N/A
Docket No.

Washington, DC
Place of Hearing

January 19, 2000
Date of Hearing

We, the undersigned, do hereby certify that the foregoing pages, numbers 1 through 262, inclusive, constitute the true, accurate and complete transcript prepared from the tapes and notes prepared and reported by Shari R. Bowman, who was in attendance at the above identified hearing, in accordance with the applicable provisions of the current USDA contract, and have verified the accuracy of the transcript (1) by preparing the typewritten transcript from the reporting or recording accomplished at the hearing and (2) by comparing the final proofed typewritten transcript against the recording tapes and/or notes accomplished at the hearing.

Date Marry Ellen Feinberg
Name and Signature of Transcriber
Heritage Reporting Corporation

Date Sophia Young
Name and Signature of Proofreader
Heritage Reporting Corporation

Date

Shari R. Bowman
Name and Signature of Reporter
Heritage Reporting Corporation