MR. BILLY: It was just suggested that I announce the availability of an overflow room. It's on this end of the building. It's 4347. There's a TV monitor in there where you'll be able to watch and hear the proceedings. I think for any people attending, particularly employees of the agency or the Department, that don't expect to be speaking I would encourage you to consider moving to the overflow room. Again, it's 4347. You go out the door here to my left and there's an L, turn left again, there's an elevator and it's a couple of corridors over so we want to make sure that everyone that wants to contribute and actively participate in the dialogue does have a chance to do so. So thank you very much.

I would like to get started now. My name is Tom Billy. I'm the Associate Administrator of the Food Safety and Inspection Service and the moderator for this series of meetings. The stated purpose of these meetings are to provide a forum for issue-focused discussion and dialogue. I'm going to work very hard to make that happen and I would argue that it's in the interest of everyone that's in this room to work with me to make sure that we have an open and focused dialogue on the key issues associated with this important issue.

At this time I'd like to introduce the Honorable Dan Glickman, the Secretary of the Department of Agriculture who has a few opening remarks.

MR. GLICKMAN: Thanks Tom. Good morning everybody. You'll notice we changed the seating format a little bit so we could be closer to each other. I don't know if that's good or not but probably breaks the ice a bit.
First of all, I'm pleased that such a wide spectrum of interests are here for the first of six issue focus meetings on the HACCP proposal. An important task lies ahead of us -- the mutual goal of improving food safety and updating the meat and poultry inspection system. It's essential that each of us keep this important goal in mind as we work over the next several weeks.

Today's agenda includes an overview of the Department's HACCP proposal, a review of FSIS oversight of HACCP, and a discussion of changing roles of inspectors under HACCP. I know that one of the key results was the request that white papers be completed for your review for the sessions. Although FSIS has been working on these papers the first one was not completed for dissemination until late yesterday. FSIS intends to have the remaining papers for this week's discussion completed for distribution by the end of today. Again, I want to remind you of the important job we have ahead of us. I intend to participate at least at the beginning of each of the planned meetings noting the importance of improving our inspection system. So I hope we can focus on the opportunity we have to reform and improve the system and avoid rhetoric. I know each of us supports food safety so we need to get to the guts of the issue and decide the best way to get there. So, Tom, I thank you very much.

MR. BILLY: Thank you very much. I'm going to make a few announcements -- some of the logistics -- give you a sense of the schedule for the day and then turn to specifically to the agenda. I indicated earlier, and I want to repeat again, that we do have an overflow room. It's room 4347. It's in this building. You go out the doors here to the left and up the elevators to the third floor and it's a
corridor over. There's a monitor in there where you can watch and
listen to all the proceedings and I would particularly encourage
people that don't plan to speak to consider moving to the overflow
room so to make sure we have space for those that want to actively
participate.

We also have a caucus room. It's a room that's just available for
anyone that wants to get together with others to talk. There will be
time during the breaks and lunch to do so. And that room is 3831.
Similarly, you just go out the doors to my left here, turn left again,
up the elevator to the third floor and it's right there on that corridor.
It's a room that can accommodate probably ten to twenty people so
any particular group of individuals want to get together to talk about
a particular issue that's being discussed you're welcome to use that
caucus room. There's a sign-up sheet out on the table so if you are
interested in like reserving it for a particular time you can do that
through the sign-up sheet that's out here on the registration table.
The restrooms, to my left, out the doors and to the left immediately
is the men's room. On the other side to the right out the doors to the
right is the ladies room so they are pretty immediately available for
you.

In terms of the schedule for today what we propose to do is to
have this opening session run from nine till ten thirty. We'll have an
half an hour break from ten thirty to eleven, then another session
from eleven to twelve thirty. We'll break for an hour and a half --
from twelve thirty to two and then we'll have another session from
two to three thirty, a half hour break from three thirty to four, and
then a final session from four to five thirty. I'm going to work real
hard to get us through today's agenda within that time frame. If it's necessary and it looks like it's important to keep going we're going to be flexible in terms of keeping the discussion going to try to bring it to closure because there's a lot of important issues scheduled for each of the days and if there's a new issue that comes up that's not on the agenda that there's a sense that it's important that we have a discussion about it we do have some time on the last day -- on the 29th -- where we can put it into that time slot and discuss it at that time.

We also have the papers that the Secretary referred to. I know that some of you didn't have a chance to look at it and to study it so what we're planning to do is after Mike opens this initial morning subject area and we have a dialogue about that we plan to go through the paper and highlight some of the key aspects for you to make sure that you're familiar with the analysis of the comments, the issues that arise out of the comments, and, most particularly, our current thinking with regard to how to address those issues. So we'll do that for today's session. If you think it's worthwhile we can do it similarly for each of the other papers that set the stage for the dialogue.

Are there any questions about logistics or time frames? Okay, great.

It is my pleasure to introduce Mike Taylor, the Administrator of the Food Safety and Inspection Service. Mike is going to open this session with an overview of the HACCP proposal with a particular focus on the philosophy and strategy that it represents. So, Mike.

MR. TAYLOR: Thank you, Tom. Let me first just join the
Secretary and you, Tom, in welcoming all of you to this meeting. I just think it's enormously important that this many people have invested the energy to be here and the commitment of time and their own work to participate in these meetings. We, as we discussed at the August planning meeting, we at USDA see just an enormous opportunity during the next several days of meetings to improve the decision-making that will lead to final rules on HACCP and pathogen reduction. We have done an enormous amount of work analyzing comments and beginning the thought process that will lead to final rules but we are in the midst of a process and we have made no final decisions and we fully expect that the discussion that we will have at these meetings will really enrich and really improve the outcome of our rule making.

I really just want to take a few minutes to provide some context for the discussions that are coming by reviewing the goals of our initiative and the principles that are invited in our proposals and our other efforts to improve food safety and really leave the discussion of the substance of the proposal and the issues -- obviously we've got six days planned to do that. I want to sort of touch though on the goals and principles that are central to our effort and I will say that based on the comments we find a rather wide agreement on the goals and principles at a conceptual level and it may occur to you to say, well, that's not too impressive, the level is in the details, but the principles that we're talking about really do involve a fundamental transformation of the system and as we paint a picture of the kind of system we envision for the future based on these principles, again, we see in the comments in a fairly wide opinion on
the principles and I just want to walk through briefly the goals and principles.

The bottom line goal, I think we all know and I think everybody shares, we want to improve the safety of meat and poultry products. We want, in particular, to reduce the risk of food-born illness associated with harmful bacteria, the principal cause of food-born illness associated with meat and poultry. We have a system in place today, as we've said, we believe contributes enormously to the production of safe meat and poultry products and has contributed enormously to the safety of the food supply in general but we also know and believe that the system can be improved and by improving the system we can work towards the goal towards improving food safety and reducing the risk of food-born illness. But that is the guiding goal for this initiative -- improving food safety.

There are about five principles or sort of concepts that we believe need to be built into the system in order to achieve this goal. These are concepts, as you will see, really go beyond the rule making itself and the specific measures that we proposed in February and really are principles that are embodied in our broad food safety strategy.

First principle is that we believe we need to adopt and incorporate into the system modern science-based process control techniques to target and to work to prevent significant food safety hazards. That's a way of saying we need something like HACCP as the operating frame work for food safety in meat and poultry plants. The targeting of harmful bacteria to achieve food safety goal is also a given within the concept of a HACCP system. HACCP is designed
process control. Preventive process control is designed to target and reduce the significant hazards. So the first principle is simply modern science-based and preventive process control needs to be the operating frame work.

Second, we believe that our system needs to more clearly define both industry and FSIS responsibilities and accountability for food safety and there are many aspects of the current system that we think blur the delineation of responsibility as between industry and the agency and its inspectors. We have a system today that is based on command and control regulation and fairly detailed prescription of much of what plants do in their daily operations to produce foods that meets our regulatory requirements. On the other hand, in certain critical areas we lack clear performance standards -- clear measures of what the acceptable outcome is of the efforts that plants are making to produce safe food and this is especially true, again, with respect to harmful bacteria on raw products. So we need to more clearly define industry and FSIS responsibilities and accountability for food safety. Again, the HACCP proposal, the HACCP concept itself was intended to address this because HACCP is, of course, a frame work within which very clear the plants take responsibility for designing process controls adequate to meet appropriate food safety objectives. The sanitation SOP element of the proposal also was part of this process of delineating what the roles and responsibilities are of plants and inspectors when it comes to insuring adequate sanitation in plants. We've got to shift, as a general proposition, as much as possible, we believe, from the command and control approach to regulation to an approach that's based on performance standards
because we believe performance standards are a powerful way to clearly articulate what industry's responsibility is ultimately and provides an objective tool for government oversight to use to hold the industry accountable for meeting clearly defined objectives. In particular, we believe that we need some tool. We think it is essential that the system incorporate some meaningful and practical measure of accountability for controlling and reducing harmful bacteria on raw product. While this was the goal of the interim targets for pathogen reduction in the proposal, we got many comments on this aspect of the proposal, of course. Very few challenged the goal of controlling and reducing harmful bacteria. We got comments from many different perspectives on the approach that we took to achieving that goal and we have a whole day set aside on Friday to discuss that issue. But the objective of having a practical, meaningful measure of accountability for controlling and reducing harmful bacteria is very central to our initiative.

One other aspect of what we're working on that supports this principle of more clearly defining industry and FSIS responsibilities is the, shall I say, long anticipated, soon to be delivered regulatory reform package of rule making proposals that will begin the process of addressing the current command and control system, the current system that is based on the FSIS prior approval of many aspects of daily operations in meat and poultry plants. We intend to begin soon the rule making that will reform that system and eliminate many of those old requirements.

The third principle that we looked to incorporate in our system is to provide greater flexibility, greater incentives for meat and
poultry plants for the industry to innovate to improve food safety. We believe that technology innovation, innovation in process control is part of the solution to meeting our food safety goal and reducing food-borne illness. We think that the shift from command and control to performance standards is the essential tool for providing the greater flexibility and greater incentives to innovate while, again, maintaining and again enhancing the role that the government inspector can play in insuring accountability. But providing greater flexibility and incentives to industry to innovate to improve food safety is a very important part of our initiative.

Fourth, we have said and we believe strongly that we must address food safety from farm to table. The proposals we're discussing today, of course, focus on the in-plant environment but we all know that hazards as well as opportunities to reduce hazards arise at every step of the food production and marketing continuum from farm to table, including with respect to how products are handled at the ultimate point of preparation and consumption and we do need to have a system and a strategy that addresses food safety at each step along the way. The February proposal included in the preamble discussion at a conceptual level of our strategies in these various other areas outside the plant, we've got a number of activities going on to compliment the rule making which, again, focuses on the in-plant environment. It's an area that we can perhaps have some conceptual discussion of. I think the last day has time provided for this. But it is very clear that we will not achieve our food safety goal ultimately unless our system addresses food safety from farm to table.
And, finally, it is absolutely essential to the success of our food safety initiative that we make better use of both public and private resources to improve food safety. The resources are finite for everyone, whether in government or in industry. It is really critical that we all focus our resources on the task that will contribute the most to improving food safety. The agency believes that the HACCP framework is a tool for all of us to better focus our energies on the critical points in the production process that affect food safety but for our agency the effort to focus resources really goes very far beyond the rule making itself. We have to fundamentally transform the way which we use our resources day to day to oversee the activities of industry. The regulatory reform rule making package will begin that process, begin to remove some of the activities, both in-plant and headquarters, that we believe do not contribute sufficiently to food safety. But we also are going through a fundamental re-examination of the institution itself and this is the top to bottom review process that many of you are very familiar with. We are in the midst of a process of looking critically at how our agency defines its regulatory roles in a new HACCP-based food safety environment, how we allocate our resources among safety activities as compared to issues involving economic adulteration, as between in-plant activities and activities outside the plant between headquarters and the field. It's time to fundamentally reassess how we allocate our resources. And it's also critical that we look at our organizational structure. HACCP is going to require an approach to decision making in the field as well as in headquarters that is different and necessarily, I believe, will need to be more expeditious
than decision making is in the current system. That alone requires, I think, important organizational change so that the system will function better. But there are also opportunities to streamline our overhead and management functions and structures to make better use of our resources to apply more of our resources on the front line of food safety functions than we do today. I think in the Federal Register of Monday or Tuesday of this week we published a notice in the Federal Register announcing the availability of preliminary reports produced by ten teams of FSIS employees addressing various topics within the top to bottom review. This effort that these employees invested in developing those reports resulted in some six hundred pages of very substantive analysis, background discussion of current programs and options for meeting the objectives that I've outlined for the top to bottom review. So in case there are those of you who don't feel sufficiently engaged by participating with us in the rule making effort we have six hundred pages of top to bottom review material that we have solicited your comments on by the end of October. And as we say in the notice, on specific topics being addressed in the top to bottom review, as they become ripe for further public dialogue we will certainly being having further opportunities beyond any written comments you may choose to submit. There will be further opportunities for dialogue on the top to bottom review issues.

As I said at the outset, the comments generally support the sort of principles that I talked about and I find that enormously important because it says that we're all working towards the same general goal. We are operating to a larger extent. I'm not saying there's unanimity
here but there's a rather broad area of agreement about some of the
general principles that need to be built into the system. What we've
got before us is a very large number of difficult questions about how
to get there and the comments did raise a number of very, I think,
cogent criticisms of our proposals as well as suggestions for how to
improve our proposals. There are a large number of issues that we
are going to have to resolve in order to get the fund rules that will
meet our objectives. I think we have an agenda that is well organized
around the principal topics -- key issues that were raised in the
comments in how we're going to get there, what's this new system
going to look like in reality and practice, and then what's the role,
what's the rationale, and how should we deal with the substance of
some of the so-called near term interventions that we proposed --
the sanitation SOP's and microbial treatments and carcass cooling
standards. So we clearly have our work cut out for us over the next
several days and coming weeks and months but we are enormously
optimistic about our ability to make good decisions and arrive at a
final set of rules that will achieve principles and goals, again, I think
very many of us agree on.

I thank all of you for participating. I'm going to be here
personally for every minute of every meeting. I'm mostly listening. I
will not be able to resist, I'm sure, the temptation to ask a question
here and there or to answer questions that any of you may have
specifically for me. But I look forward very much for the next six
days of meetings. Thank you.

MR. BILLY: Okay. I'd like to now before we open it up
specifically to the initial items on the agenda as well as any
observations or discussion on Mike's comments, I'd like to review the
ground rules that we published in the Federal Register. I think these
ground rules are important to all of us and I'm going to work very hard
to make them work for us.

First -- you know -- what we said is we want focus discussion
and dialogue on the agenda items. I'm going to come back to the
agenda in just a moment but I think that's the frame work in which I
think we can accomplish what we're here to do.

Also I'm going to work very hard to have an open and balanced
exchange of views. We're going to have a process that I'll explain in a
minute of recognizing people in terms of speaking but to the extent
possible we'd like it to be an open dialogue and people really talking
about a specific issue and I'm going to work real hard to do that and if
I feel, based on the comments I've reviewed, that there's another
point of view, I'm going to elicit comment to get that point of view
out on the table so that in that sense we're focusing on all the
different perspectives on a particular issue. I'm going to work hard
to stay within the general time frame and keep people focused on the
specific point of discussion. You're going to have to bear with me on
that. I'm going to work hard to make that work.

I encourage people not to make repetitious statements. If you
make a point let's provide time for others to react and provide their
point of view as well. It's clear from the comments that we've
received and the scoping sessions that a number of interests have
been raised with regard to legislative changes. If discussions -- if
people bring up points that relate to a need to change legislation I'm
going to request that that be deferred. The Secretary is planning a
food safety forum in October and there will be ample opportunity for
everyone to present their views in terms of legislative changes of the
opportunity to talk about how legislative change might facilitate
what people are trying to do in terms of the current system as well
as how this system might be improved.

The way I'd like you to seek recognition and I'm going to try to
keep track is through -- -- so it's kind of getting in international
form. If you want to make a point on a topic hold it up and I'm going
to look and I'll get your name and then keep track and make sure that
all of you have a chance to speak. And I know it's a little burdensome
but I think that way we'll maximize the possibility of everyone being
heard. When you do get the microphone please state your name and
your affiliation. That's important for the court reporters because
this is all being recorded and will be part of the formal record so it
helps them identify specifically who is speaking.

Finally, prepared written statements. This isn't the forum for
taking the mike and reading a several page written statement. If you
have a written statement we welcome it. We've opened the record for
this rule making. It will be open for thirty days after the last
meeting and we request that you submit it to Dockets. The Docket
Office is here in this building. People at the desk can tell you where
it is and it can be formally submitted. It will be read and it will be
considered as part of the final rule process so it's not that they're
unimportant but this is about a dialogue and about focusing on real
key issues that I think all of us want to work on to try to resolve.

Okay. Given that, what I'd like to do is to open the discussion. I
want to refer you to the agenda. Look at September 13th schedule.
The things that Mike talked about in terms of the general philosophy are open for discussion but I'd like to approach it in the context of the agenda and focus initially on the first item -- Item A -- the near term measures. Now this is a discussion about the role and rationale of having near term measures, not the specific -- well, we don't agree with the temperature you propose for -- we're going to have that discussion at a later time. This is a discussion, hopefully, about the idea of having near term measures while HACCP is implemented over a several year time period. So with that I open the floor and encourage comment on that question and on that issue.

MR. DRYDEN: Good morning Mr. Secretary. My name is Forrest Dryden. I'm Vice President of Research and Development for Hormel and Company based in Austin, Minnesota. We appreciate the opportunity to be here with you this morning and discuss these important issues and to have the staff here and hopefully have this dialogue.

What I'd like to do is give you a bit of my background. I have an undergraduate degree in Animal Science and a couple of graduate degrees in Nutritional Biochemistry and Meat Science and wound up with a Ph.D. finally. Started out initially in my career working in academia -- ten years at the university teaching these courses in food science and meat science, both graduate and undergraduate level courses. Then I had the opportunity to visit this great city for a couple of years. I worked on the AMI staff in the technical and scientific area interacting with the Department and the industry and then most recently now I've been at Hormel for fourteen years working in the research administration area but also as the chief food
safety officer of the company.

During this fourteen year period on a number of occasions I've had the opportunity to interact with the staff at FSIS and even to serve a few years ago on the meat and poultry inspection committee as one of the committee members. Hormel Foods is a Fortune 500 processor distributing not only meat items but other food products nationwide. We slaughter annually about ten percent of the pork and further process most of that product. We also have a wholly owned subsidiary, Jennie-O Foods, which is a major poultry or turkey processor located in Minnesota also.

What I'd like to do this morning, since we didn't have others that were volunteering, is talk with you a little about HACCP and share some of our views on this important subject. I don't know how familiar you are and whether you've ever been able to really use the process but I think we're impressed with it. At the outset I'd like to insure you that we have implemented HACCP. We are using HACCP at Hormel Foods and we have for a number of years. We are pleased the Department has published. We have worked with AMI to petition for HACCP, to use those principles in our business. We need that. It's important that we have a cooperative approach to implementing HACCP across the industry. It's just not going to work if we're not working together to further develop what's already in place in terms of food processing and what we're doing with HACCP. We worked very hard, as Michael pointed out, to build prevention in our processes. We do that wherever we can at Hormel as do other processors and I think if there's one thing we've learned over the years is that we do not test these problems out of our products. We prevent. We build
prevention into them. We might use a thermal process, we might use
a PH control, some kind of a hurdle in many cases as part of the
process so that we have that prevention mode in place. We also put
our name on each one of these products and we are responsible for
those products in the marketplace and we take that responsibility
very seriously.

I'd like to just for a minute give you an example -- a working
example or two of HACCP -- how it might seem like a relatively new
term but I think Pillsbury in the 1960's coined it. Maybe Howard
Baum in there was responsible for coining the term HACCP. We've
used in the acid canned foods producing Hormel chili and Spam for
over fifty years. We like the discipline that we've incorporated in
there that has developed through the trade association. In the early
days going back in the 20's and 30's there were significant problems
with clostrating -- -- and an understanding how to control that
organism and other pathogens. When you control that one fortunately
you take the others out. Those GMP's were developed through the
National Canners Association better known today as the National Food
Procecssors Association and those were shared with FDA and in the
70's those GMP's for low acid canned foods were formalized and in the
mid 80's USDA formalized those same guidelines. I think they have
served not only the industry but consumers and others as probably the
leading working example of how HACCP will effectively operate in
the food chain -- how it can work there. There are other examples
that I could use this morning and I can get into the detail if we'd like
to do that but we can talk about roast beef and how we use HACCP to
produce that kind of a product; cooked patties; we can talk about dry
sausage and we can get into any one of those, but I don't want to use
more than my share of the time here. I just have a very firm
conviction that prevention is the mode that we need to be in and when
I say that, in fact, we put our name on these products, they're before
the consumer. If Washington thinks it has a contract with America
we have a contract with individual consumers out there. And if we
tarnish that more than once or twice and there will be errors. I don't
care how well we adapt HACCP and develop and science is always
developing there will be some areas. But if we tarnish that name out
there we're no longer in business. And that's the motivation that
drives our conviction behind HACCP and how it works and where we
ought to really be. I would agree. There are some areas where we
need to all improve and we'll do that but we do that when we have the
interest of the consumer at heart. You know, that contract or that
consumer, we can't violate that and we'll move those processes
forward and I know that we're not at the end of all of the
interventions that we're eventually going to find to use with these
products. But we've got to have the flexibility, and as you mentioned
Michael, it's part of the plan to let innovation work some more here.
Frankly, we've all been pretty constrained and we'll bring some more
of those interventions to the front that will help us and we'll build
HACCP plans around those. We'll put the stop signs in there and when
a process is not functioning properly make those -- when a process
deviation occurs we'll correct that.

So with that I would just leave you with those thoughts that we
apply what we're doing. I know you asked that the near term
interventions be the initial focus here and I've intentionally done
what I've just done and I think those near term -- that focus is part
of HACCP. We're going to be doing all of those things when we have
HACCP in place and whether -- and it's hard to decide where you need
to be with all of those details and I don't mean to slight details but
frankly that's what they are in the scope of the big picture of putting
those interventions or having those processes in place to insure safe
foods. Thank you.

MR. BILLY: Thank you. Lee.

MR. JAN: I'm Lee Jan. I'm the Director of the Texas Meat Poultry
Inspection Program. I'm here as a representative of NASDA and the
National Association of State Meat and Poultry Inspection Directors.
I would like to address some of the near term measures just real
briefly -- maybe some philosophy -- but we totally agree that HACCP
is the way to go and there has to be a transition period and I think the
near term measures are a way or a step to get there. I do believe,
however, that there are some -- you're kind of reluctant to give up
the command and control and I think that in the near term FSIS does
need to start giving up the command and control and what I'm talking
about is the mandatory requirement for carcass washing. I think that
rather than mandating carcass washing that should be authorized or
allowed to be a process that the plant chooses to improve but don't
add more command and control. There are probably several or many
processes that without carcass washing are doing a great job in
meeting the goals. We just don't have the data to maybe to back that
up at this time. And speaking of the data, the testing is another near
term issue that tends to be in command and control and I think when
we think about if it wants to be a commanded requirement then that
commanded requirement should be at the cost of FSIS. When you allow it to be optional or to be a process -- a part of the process as we expect with HACCP in the future, then those tests that would be required to verify that that's working should be a part of the plant's responsibility. But to make a command decision that every species every day, regardless of volume, is going to tested and we're going to make the plant pay for it, we're saying -- we're giving you responsibility but we're telling you how to do your responsibility and, although we need to have guidelines, if FSIS is going to make those demands then they should pay for them and if we allow or move to voluntary testing to verify their own processes that should be paid for by the plant as part of their process and verification as has it's always been. Currently we test for economic -- you know -- percent fat, water, or whatever. FSIS pays for that and we go to the more expensive testing where we're looking at maybe putting some people out of business if you say you have to test every cow that you kill. If you're a small business -- you know -- that's just going to be cost prohibitive. So as long as the process or the plant's process can't dictate the time for the testing or the frequency of testing then I think that should be, again, paid for by the FSIS.

Now, standard operating procedures, that to me is a great move toward relinquishing some command and control. Now you're telling the plants -- you know -- you have to take control, you write up what you're going to do and we're going to look at that. That's the way we need to be going. Let's go with standard operating procedures written by the plant with some input from FSIS or from inspection programs because of the expertise and the background and can see where it's
going but let the plants put it in motion and then let FSIS or state
inspection programs verify it's working. But I think that's what we
need to be sure that these near term objectives do start relieving
command and control in those places that it can't be and it still has
to be felt that it's directed then if you're going to direct it, make it
mandatory, then pay for it. Thank you.

MR. BILLY: Judy.

MS. ST. CLAIR: I'm Judy St. Clair, FSIS inspector. I know that
you say that you published six hundred pages of your top to bottom
review. Can you tell us briefly what your day one plans are for
implementation?

MR. BILLY: What I'd like to suggest, Judy, is that the next part of
this day's agenda is on the inspection -- how FSIS inspection will
work and more specifically those kinds of plans so if it's all right
with you I'd like to hold off on that. We'll come back to that. It will
be addressed but I'd like to, if possible, keep this discussion on sort
of the philosophical underpinning of this approach and the general
questions -- is it appropriate, is it necessary, a good idea to have
near term initiatives while HACCP's being implemented, views about
HACCP, the general sense of merging HACCP into the inspection
system that as we have it now, the items that are here under A,B,C,
and D, and timing as well. So, we'll come back to those. It's an
important point.

Who's next? Rosemary?

MS. MACKLOW: I'm Rosemary Macklow, Executive Director of the
Meat Association. The issue here today is not whether HACCP is the
goal for the future. It is rather how do we retool today's meat and
poultry industry away from the expectations of the traditional procedures and towards accepting HACCP responsibilities and what is the role of government in that process and there are several things that we have to address if we're going to make this transformation efficiently and effectively to meet our common objectives. That's what we're here to talk about.

The first essential element is the realignment of the responsibility for food safety. Government-imposed regulations calling for HACCP cannot, have not, and will not make an industry accept its responsibility for producing safe food. HACCP is a process control, clearly places the responsibility with the industry, and if applied correctly it will enhance food safety. Monitoring and auditing of the systems is the proper and appropriate role for the government. TOPS, anti-microbial treatment, all of those things can be part of this. They've got to be driven by the company and we have to understand what the government is going to do as part of it. Much of the debate of the last few years has suggested that nothing has changed since 1906 or even 1967 and that really nothing could be further from the truth. I mean an enormous amount of stuff has changed and while the relationship between the Department and the regulated industry is necessarily and appropriately one of an arm's length, the every day working relationship where they stand shoulder to shoulder is one of professional cooperation. As we make change for the future it's essential that in this working entity that we know exactly what the authorities and the responsibilities of each other are.

In the new roles we are concerned that there is set forth in the
regulation a great deal about what the industry must do but it speaks
very little about the role of what the regulator is going to do. There
are two elements to the new role of the regulator. First, the
inspector's primary job should be the verification that each
establishment is performing according to its HACCP plan. Second, but
equally important, is that the issue of layering needs to be addressed
so that inspectors are not using the time and energy released by a
HACCP system to perform other obsolete inspection tasks that have
been replaced by HACCP.

To meet the new roles, I want to assure you that our industry is
moving aggressively forward in learning about HACCP. Its managers
and supervisors are involved in training. We have another training
class at the end of this month which is already sold out. This
industry is out there learning about HACCP and it's very exciting. We
want to know what you're going to do to train your people in HACCP
because one of our greatest concerns is that we may be there and
they're flying by a whole different airline and there isn't the
interaction and the interrelationship. We're very pleased that the
international HACCP alliance is about to conform its accreditation
procedures for HACCP training. This becomes very important. But
where is the Agency going to fit into this process? Are you going to
have the same standards or are we all going to be at six's and seven's
again? Because it doesn't make for an efficient industry if we're
arguing over differences of who sees the way the concept is shaped.

We've heard some rumors about day one. We've read some things
in the trade press about how things will be but we still don't have an
understanding particularly at the plant level and it's terrifying to
small plants if they've always approved by blueprints for ninety years and now tomorrow they're not going to do that anymore. What authority does this give the local inspector in the plant? Can he come in because he doesn't like the drain or something or other and he can stop that operation? These are very every day working relationships and that's just one of many, many of them. How are you going to convert that field force? I don't want to be repetitive because you're rule me out of order.

The implementation of HACCP needs to recognize the special needs of small businesses. Small businesses are companies with limited numbers of employees and limited access to capital resources necessary to do the retooling. But they have an enormous investment in their community. Like Hormel, they're known people, know where that product comes from, the family name is known, they're generational companies. We can't just suddenly make up regulations that's going to make it either costly prohibitive or inspector prohibitive in terms of how they're going to fit in to that future relationship.

The 1906 social reforms of Upton Sinclair inspired that first mandatory meat inspection law. The '67 amendments were dubbed the wholesome meat act and they respond by the unlawful entry of horse meat into the school lunch programs. We're not here today, as you properly said, to design changes in the statutory authorities but we are doing something that may be a precursory to that and I noticed Dr. Goldberg not far behind me listening carefully. We are looking at issues that were energized by a very serious illness and death to our nation's most precious resource and that was children who ate
improperly prepared hamburgers. We, as an industry, want to do it right. We want, as Secretary Glickman's mother admonished him, to make food safe. We are but one segment in that long food chain from the farm to the table. We want to do everything reasonably possible while the food is under our control to make it safe. That's why we're here today. That's why I came back from New Zealand and I'm not quite sure what day it is. That's why we need to hear from the Department how its plans to carry out its part in this effort. It has kept me awake at nights -- not really, but almost -- worrying about that issue because I know the day to day stuff that is going to go on in plants and a lot of people around this table are equally concerned.

Thank you, Tom.

MR. BILLY: Observation, Rosemary. As you look at the agenda, probably later this morning, there's a plan to get very specifically into that area of the role of inspection and the specific role of inspectors under both the near term measures, however they sort out, and HACCP, and it will include a fairly detailed discussion about what you've heard about in terms of day one so that will be part of today's discussion and in some depth. So I'd like to sort of defer that till we get to it and provide everyone a chance to make any observations about the general philosophical approach that's here and these initial items.

Caroline?

MS. DEWAAL: Caroline Smith Dewaal, Director of Food Safety for the Center for Science and the Public Interest.

In 1985, the National Academy of Sciences Report was issued that first called upon the implementation of HACCP for meat and
poultry products. Since that time we've had ten years of outbreaks and of illnesses. We don't know to what extent HACCP will prevent those but we all have a lot of hope that once it is implemented we will see a major reduction in food-born illness and outbreaks.

Everyone agrees that HACCP is a long-term objective here. The question is, given that we are ten years behind the ball already, are there short-term initiatives, things that exist, things that work, and things that can easily wrapped into HACCP once it is ready for full implementation, things that can be done today or tomorrow or in a year from now? If those exist they should be used and I support FSIS's approach to looking at short-term, near term initiatives that will have a food safety impact and that can be used soon rather -- sooner rather than later.

MR. BILLY: Barry.

MR. MARSHALL: Yes, Mr. Chairman. Thank you for this opportunity to attend this very informative conference and I think the outcome's going to be extremely good. I'd like to say that I am from a country, New Zealand, which, of course, is one of the major exporting countries in the world for sheep and beef and we export eighty to eighty five percent of everything we produce. I won't tell you the jokes about the number of sheep as per population. However, we're very supportive of the measures being taken by FSIS to improve food safety. We know, as an exporting country, how important it is to make sure that your product is acceptable. In this respect, there are a number of issues here that certainly fit in with New Zealand's concepts, although we may defer somewhat on how it's actually achieved. We agree in the principles, the end results, and we have put
forward a fairly substantive submission suggesting that in the New Zealand situation, which is totally different than we do things here, that we can actually achieve the same end result as what is trying to be achieved here.

I just quickly would like to say that in terms of the mere measures or initiatives for the rationale of sanitation standard operating procedures, anti-microbial treatments, carcass calling, and all that sort of thing, certainly we feel those -- a number of those issues need to be addressed and certainly in the near term.

One of the issues that we feel that -- and I was just -- the previous speaker was making comment that a number of these things can be done right this moment and it was also mentioned by Rosemary Macklow about farm -- right from the farm gate through the system but we've identified in New Zealand that unless you actually present your stock clean for slaughter, clear of all the fecal matter and contaminants and everything else, then you're going to have a problem in terms of the initial bacterial loading on the carcass as soon as the hide comes off. In New Zealand we are a little bit fortunate because our animals are grazed outdoors so they defecate in one spot and they lie down in the grass somewhere else. Here it's feed like cattle and so there is a major problem and I personally recognize that and this is something that needs to be addressed by the industry on how they're going to actually clean the animals up -- at least the knife cut areas on hides and what have you -- to actually minimize that initial contamination going on to the carcass. This whole issue about standard hygienic standard operating procedures goes without saying. Unless you have a hygienic environment and unless you're -- it's
maintained clean throughout the processing, unless your employees know what they're doing and know what is right and what is wrong then it's going to be an uphill battle so I think that those are issues that industry can be addressing right this moment without any input at all from government.

In terms of carcass chilling and freezing requirements it's quite a standard to me that this country really has only on the books one chilling requirement or one requirement as far as temperature and that is actually the temperature at the cutting room facilities. Now, New Zealand's found -- well, simply because we're transporting meat so fast -- that really you need the chilling regime to occur so that the carcass temperature decreases the moment the hide comes off and viscera comes out so you've actually got a decreasing temperature curve and that's necessary to reduce this level to a level where the bacteria don't multiply. So we are very supportive of what is being proposed in this initiative about temperature reduction.

We're totally opposed to the parameters that are actually being described. That's an issue we'll take up later on. We consider that seven degree celsius which is forty five degrees fahrenheit is against 4.4 celsius which is forty degrees fahrenheit is much more practical, cost effective, and everything else, but that's another issue.

In terms of -- well, generally, I'd just like to finish at this point of saying that New Zealand's very supportive of what's been done. We feel that the principles of HACCP need to be applied but many instances we're actually talking about good manufacturing practice. We, in New Zealand, are not going to mandate the use of HACCP but it's quite interesting just by virtue -- well, we're not
going to mandate them simply because we actually have mandatory requirements for certain things in the system anyhow and when you actually collectively bring them together perhaps that's somewhat similar. However, the idea of good manufacturing procedures, industry responsibility for controlling these, and the import by the controlling authority to monitor it I think is the most effective way of going. Thank you.

MR. BILLY: Just to let you know I've got Kim Rice and Dane and Larry and then Tom. So, Kim.

MS. RICE: I'm Kim Rice, the Regulatory Affairs Manager for Jimmy Dean Foods. Jimmy Dean Foods is a major processor of nationally branded and private labeled hot boned pork sausage and for twenty five years we've been committed to providing our consumers with a high quality and safe pork sausage. It's with this commitment in mind I'd like to offer the following comments on HACCP programs in production facilities.

As you may or may not know, our product goes from a live animal to a finished consumer-ready package in about an hour. Our process is continuous from the time the animal is bled and then skinned, eviscerated, boned, blended, final ground, packaged and frozen for distribution. By the nature of the process itself we capitalize on our processing time to minimize the ability of harmful bacteria to grow. Our process is unique and when compared to other hog kill and processing operations as if often the case under the current set of regulations and the proposed regulation we're faced with the challenge of making a one size fits all regulation work.

However, with the HACCP approach we're able to embrace our
uniqueness and focus our resources on the process rather than on the regulation. We feel a focus of resources by the industries and the agencies on the implementation of HACCP systems from farm to table will be more effective in reaching both our shared goal in producing a safe and safe meat and poultry supply to consumers.

For example, and more specifically to our process, the proposed regulation would require that we sample for salmonella on a daily basis on the kill floor and then again approximately twenty minutes later from the ground product. This doesn't make sense to our operation and it's once again taking one size fits all approach. Under our HACCP approach we would be allowed to determine at what point and the frequency at which we should sample for microbiological testing to validate and verify our HACCP plan. Our HACCP approach allows companies and, in the end, the agency the flexibility to create a food safety system that is individualized for each situation rather than once again trying to make a one size fits all regulation work. This flexibility should be kept in mind when creating any HACCP regulation and modifying any existing regulations. The nature of HACCP itself will allow processors to analyze their individual product, process facility, etc. and lends itself to creating a food safety -- excuse me -- a food safety system that is compatible with each operation. For instance, the hazards associated with the older animals similar to the raw materials we use are different than those with typical hog kill operations that use younger animals.

In developing our HACCP plans we have taken this into consideration when doing a hazard analysis. In addition, the hazards and the point at which those hazards enter into our process are much
different than those from typical hog kill operations. Therefore, we feel mandatory critical control points should be avoided to allow processors the flexibility and in the end the agency to create programs that are more specific to individualized processes.

MR. BERNARD: Thank you Mr. Chairman. Dave Bernard, National Food Processors Association. If I can be so bold as to deviate from the current course and address near term initiatives specifically.

The comments that the National Food Processors Association filed did not favor the use of mandatory interventions. The philosophical reason for doing so was not that we disagreed that many of the interventions suggested didn't have technical merit. We think that they do have technical merit. As Lee Jan alluded to earlier, we viewed them as an extension of the current command and control mentality which must change if we are to fully support and fully commit to HACCP down the road. That was the philosophical reason for doing so. We just did not find it totally compatible with what we are proposing to do here and I think we all are in agreement that the vehicle to take us to a safer food supply is HACCP and I would suggest that what we do from this point on should be supportive and compatible with that concept.

I would also like to suggest that when we find technical solutions that should be implemented, and I think the agency has provided leadership in identifying several of those, that maybe we try to explore the vehicles which seem to have been forgotten and that's a way of getting compliance without using the command and control approach and that's by gaining consensus that these operations, our interventions do in fact work, and get them adopted as soon as we
Thank you, Mr. Chairman.

MR. BILLY: Larry.

MR. BERMAN: Mr. Billy, we've met before. My name is Larry Berman. I'm with the United States Department of Agriculture, Food Safety Inspection Service, and I'm an inspector in charge out in the field.

I want you to know I'm not here as an inspector. I'm here as a volunteer on behalf of several consumer groups -- Stop Gap and the Safe Food Coalition among -- a few among the many here. I am here as a subject matter expert to describe some of the conditions out in the field and some of my experiences. Okay.

Mr. Dryden said at the outset in some of his opening comments that further development of what's already in place is needed and I believe that to be true and HACCP is the key.

Ms. Macklow calls that layering, implying that's old paint or new paint on old paint. I wholeheartedly disagree. I suppose she also -- I further stated that this -- we should be there in a less of a regulatory role and more of verification role. This is an honor system we're talking about and honor systems historically do not work. They fail. We need the eyes and ears of every inspector out in the field.

Just a few experiences that I've been asked to relay. Recently, I was in a plant and I saw in the staging area a product that looked suspect ready to be included in product. I tagged it. It was sampled and it was found to have a six percent insect infestation. Had I not been there that product would have been included and been out on the street. Within the same couple of weeks over a thousand pounds of ground beef that I found to be suspect that was in the staging area
ready to be included in product was found to be by laboratory analysis
with a bacteria count such that it was determined that it was in fact
off condition.

I would like to agree with Ms. Macklow that we do fly different
airlines. My airline is consumer protection proudly. Thank you.

MR. BILLY: Tom.

MR. DEVINE: Thanks. I'm Tom Devine with the Government
Accountability Project. My comment is also triggered by Ms.
Macklow's remarks. Her question was on the role of the inspectors
and I think it's fairly common sense that what the role of the
inspectors has to be. It's to keep the HACCP system honest.
Somebody's got to do it and that's the role of the inspectors. Whether
or not we're layering efforts at honesty depends a lot on questions I
would have and I'm looking forward to hearing answers to from the
industry representatives here about what they are planning on doing
to keep the HACCP systems credible and reliable. If the organization
were to work our primary philosophy is that sunlight is the best
disinfectant. But the meat industry is particularly dark in terms of
public oversight. This is an industry which will not let the public go
in its plants, will not let the public see public health records, will
not let workers have job rights against being fired for raising public
health concerns. At the previous HACCP round table I'm strenuously
opposed having any type of internal corporate structural autonomy for
the enforcement personnel who will be responsible to keep those
HACCP plants credible in practice as well as on paper. It's very
difficult to have very much confidence in industry without federal
inspectors keeping it honest under these circumstances. If we've got
layering it's a paper thin layer versus a thick blanket and I want that
blanket to keep me warm quite frankly. But I know that all of us are
coming to these meetings very open minded. We have a lot to learn
and what I'm looking forward to learning over the next few weeks is
the industry's plans to keep their HACCP programs honest and credible
even for the weakest links in the industry, those few plants who are
willing to make money off of unsafe meat and poultry. The details of
the industry plans from their international HACCP associations and
conferences and meetings will be very educational for us in depending
how much responsibility the industry's willing to assume. That
creates a direct link to how much we have to rely on the federal
government.

To go back to the earlier analogy of sunlight is the best
disinfectant. Right now we have the inspectors. We have inspectors
who are flashlights -- consumers' flashlights. There's eleven
thousand flashlights trying to keep our food safe. It would be very
inspiring over the next weeks we learn about a thousand points of
light from the meat industry. Frankly, I would be satisfied if they
would give us four points of light -- access to plants, records, job
rights, structural independence on public health related issues.
Unless we get those, unless we have those vehicles for
accountability, there is no substitute for having just as strong an
inspection force as we have today.

MR. BILLY: Mike Taylor.

MR. TAYLOR: Lest we duplicate the May hearing and the agency
sits passively by while the conversation goes on I just want to make
an observation or two about what I've heard hopefully for the purpose
of fostering some dialogue and inviting -- you know -- inviting
further comment, criticism, suggestions.

On the issue of inspection, as Tom said, the agenda provides for
some really detailed focused discussion later today and my guess is,
tomorrow as well, on the issue of how the agency, in its current state
of thinking, envisions inspecting HACCP. The one observation I
wanted to make is that I think it was clearly laid out in the preamble
to the proposal and it's certainly something that I've talked about a
lot since and that is that we regard maintaining a very rigorous
inspectional oversight program to be absolutely essential to the
success of HACCP. We, in fact, believe and our budget strategy is to
maintain the kind of inspectional resources in terms of numbers that
we have today. What we also believe is that we need to
fundamentally change the way in which the inspectors play their role
in plants and in other areas where there's an opportunity for
government oversight to contribute to food safety. So without
rigorous credible oversight I don't believe the HACCP initiative will
succeed. I don't think we'll achieve either our food safety objectives
or respond to the public's very persistent expectation that there be a
credible system of oversight. So the issue from the agency's
perspective is not whether there will be rigorous inspectional
oversight, it is how do we do that, what are the best roles
government inspectors can play in overseeing HACCP and other
activities in insuring food safety and meeting other consumer
protection objectives. I say we're going to talk in detail, both about
our current thinking, but then also have discussion about how we
ought to be inspecting under HACCP.
I have a question, I guess, I'd like to pose about the near term interventions and just maybe raise the question by way of sharing a little bit more about motivation for them and the thinking that was going on in our heads as we drafted the proposals and I'll use the anti-microbial treatments element as an example of this and, again, I say this for the purpose of inviting some discussion and some reaction. We are going to have a whole session devoted to anti-microbial treatment so, again, the issue is not the details of how we've done it but the concept.

One of the things that I was struck by when I came in last fall was the extent to which the industry was telling me was that we want to be using interventions of this sort to improve food safety and, indeed, the central thrust of what I was hearing is that the agency was an obstacle to companies incorporating these technologies and we got very focused as a result of an element of our strategy in looking at how we can get out of the way of useful innovation and some of the proposals so that you'll see to illuminate some of our prior approval procedures all together are aimed at that.

But what also became evident, at least the idea that formed in our heads was, there seems to be among the companies out there trying to incorporate -- you know -- available technologies to improve food safety. There seems to be -- at least one could assert -- that there was an emerging standard of care that says that in light of where we are today technologically, in light of where we are today in terms of the condition of animals coming into plants, in terms of the degree to which they're contaminated externally as well as in some cases infected with pathogens internally, in light of the
practical reality of slaughter processes there seemed to be an emerging standard of care that said we ought to be looking to incorporate an anti-microbial treatment in the systems a way to make a contribution to reducing harmful bacteria and thus improving food safety. So the question we asked ourselves was well, if this is - - if we're right about that, if incorporating these technologies is an emerging standard of care and if, in fact, these technologies are available and do make a contribution, should there be in the near term as a way to begin making progress towards improving food safety as we implement HACCP over the long term, the question we asked ourselves should we establish -- really codify -- that standard of care for the whole industry and the answer we came up with, obviously, in the proposal was, yes, we should codify for slaughter plants a single effective anti-microbial treatment. And there are a lot of issues about whether that command and control approach, which I confess it is really -- you know -- makes sense, both near term and long term in light of our performance standard and HACCP philosophy. But the question we're grappling with is, if we know there are tools out there now that can improve food safety now as we move towards HACCP and if, in fact, we can see that this emerging industry standard of care to incorporate these, what is the role of government in seeing to it that in the near term we make progress where progress is available to be made to reduce risk and that in sum and substance was the spirit and philosophy behind proposing the mandate anti-microbial treatments in the near term. And I just assumed -- I mean some of the discussion with us between parties about that philosophical approach, I think, would be helpful to us as
MS. MACKLOW: Tom, may I just make a very brief comment. My recent only experience down there in Barry Marshall's country demonstrated to me some very interesting things. They are not into the anti-microbial treatments that we are looking at and the issue becomes one of a performance standard and if they can get a total plate count on their end product on a consistent basis without that anti-microbial treatment there is no reason why our government should be saying, okay, thou shalt do this and it is command and control. They have different conditions. They don't have Nebraska mid winters with balled up cattle, although two days ago I went to see a plant where they did have some balled up cattle where they're shaving them on the floor, but those animals had also gone through -- and I saw sheep going through two baths in the live sector and I had never actually seen this before -- maybe I haven't been looking properly when I walk around livestock pens -- but these animals were literally walking through a bath and did it twice before they went into a kill plant slaughtering at a hundred and twenty hour a day or something. It was a substantial number of animals that were actually being processed so that they brought them into that plant treat. It won't work in Nebraska. Maybe Colorado. The winter months for the big heavy cattle are very difficult but they had some animals where they were shaving the underside of the animal on the kill floor in order to once again give them that opportunity to have a clean cut into the hide and to pull it away properly. There are many ways of getting there and we have to decide. Are we going to be descriptive or are we going to have standards that people are going to meet?
That's the issue. You can't have both in the HACCP system. You're either going to have a prescriptive system or we're going to have a meat goes in standards for certain kinds of numbers.

MR. TAYLOR: Just for the sake of dialogue. The notion that you have adequate performance standards that address the safety issue that a current command and control idea is intended to address that obviates the need for the command and control requirement and that's the whole philosophical construct here of our strategy. The issue is, in the near term -- I mean this is what we discussed when we talk about anti-microbial treatments for several hours -- but the issue is when we're going to get to meaningful performance standards for controlling or reducing harmful bacteria and whether in the meantime there's for food safety sake there needs to be some residual command and control in the system. I mean that's basically the policy question that we're grappling with.

MR. BILLY: Ron.

MR. PRUCHA: I'm Ron Prucha. Four years I was occupying Mr. Billy's chair in the program. I retired in 1992 and was acting administrator and have been occupied since in retirement activities and also consulting with the industry primarily in the areas of government inspection and plant management relations.

I see the interventions as something that should rightly be separated from HACCP as it stands -- the HACCP proposal. I would make a guess to say that there's probably almost unanimous consensus or unanimity among the attendees at this conference that HACCP is the way to go. That everybody agrees with it as the best thing in the system for improving food safety and that it should be
implemented. But all of the interventions and all of the, what I would
term, bells and whistles that have been hung on to the HACCP concept
are what the controversy seems to be about.

The command and control, to use your terms, the system of
inspection that has been practiced for some ninety decades -- the
ninety years up to this point has become very well entrenched in FSIS
and the inspection system. It is there today and I think while
everybody will agree that HACCP is a great concept, there have been a
lot of others -- other concepts that have been out to the field that
are in use today but that the implementation, the training, and the
administration of these great concepts have left a lot to be desired,
certainly at the plant level for inspection and the industry. And by
those I would include PEA, zero tolerance in beef, and pre-op
sanitation, the way that I see it as being those have been carried out
in the field at the present time.

The agency, in my opinion, has a lot of work cut out for it -- a
lot of work -- some of it very time consuming. And much of it, I
think, is centered around changing the mind set of inspectors,

supervisors, the field people from a hands on do it yourself type of
control system to one of verification and monitoring which HACCP is.
I think the industry can do it. They are anxious to do it. They can do
it well if given the chance but they need a lot of guidelines, less
prescriptive command and control things which I personally feel that
the interventions are. These interventions are good and we'll talk
more in detail about them as they come up in the days to come but I
believe they are good but they should be part of a plant's HACCP
system and a HACCP system can well control most of the things that
you're trying to get done.

#2 MR. BILLY: I have now Dane, Ken, Myron, and Steve. But I'm going
to -- and Nancy and Caroline. But I'm going to call the first break and
be back at five minutes after eleven.

(A brief recess was taken)

MR. BILLY: I'm going to convene the session again. I'm going to
suggest a slight modification in the form that the meeting is
following just to try this and perhaps it will help. We are very
interested in a dialogue and there was a little bit of that when Mike
spoke and Rosemary offered a comment specifically back on that. I'm
going to continue to recognize people but if someone has a comment
they want to make on something that's just been said that is right on
that point speak up and I'm going to -- I'd like to work with that and
see if that -- in that way we can enhance the dialogue even more so
while there would still be some general structure in terms of
everyone having a chance, if it's right on point and we'll facilitate the
dialogue then I'm encouraging people to be recognized beyond the
order that I have for people to comment and we'll see if that works.

Also, of the early comments that we received, to get things
started, to break the ice, I did cut a little slack in terms of
statements but I'm going to tighten it up a little bit in terms of
really getting specific comments on these issues, not a lot of
background about companies or associations or organizations of
various types. It's important to identify who you're associated with
but let's try to stay -- use this time to the maximum extent we can
to focus on the issues.

The next speaker will be Dane. Dane, we can't hear you.
MR. BERNARD: This is Dane Bernard, National Food Processors Association. I will speak to near term measures which is where we started and Mr. Taylor brought us back to that just before the break but I can't resist making one comment that I want to be very clear on in response to a note made earlier. The industry does not view this as a system which can work if it is left as an industry honor system. That's a misperception but must be corrected. Mr. Taylor addressed this very well in that there will be an inspection presence. I liken it to taking in the Washington area -- all of you can relate to this -- liken it to taking all the speed limit signs down and trying to cruise the Beltway without state police out there. We don't want that. No company can exist with the playing field being unleveled and being tilted towards those operators who would take advantage of the system. What those roles will be under a HACCP system we need further definition as do the inspectors. Today we probably cannot come close to having a full picture of that. But let us be clear. The industry does not view this as an industry honor system and industry self policing.

Back to near term measures. The note was made earlier that the devil may well be in the details. There is obviously a philosophical point of view here which made earlier that we see this as running counter to what we want to accomplish with HACCP. HACCP is the vehicle which is to get us to a safe food supply. We need to commit to that, not give it tepid support and continued command and control but give it full support as we move down the road. There are obviously some good measures which have been identified and should be probably adopted but all of those measures, as was said earlier by
Kim Rice, are not going to be applicable to every segment of the industry and mandating them across the board returns to command and control where we will be making decisions for certain part of the industry where those decisions simply don't make sense. And some of them, as you well know, are very controversial. The temperature requirements are very controversial. And if anybody in this room can tell me the difference between the risk factor associated with a load of ground beef trimmed that comes in the back door at thirty nine versus forty one I'd like to see that information. So there are things which don't make exactly scientific sense in those measures which further blur the future role of HACCP in setting up critical control points and critical limits that make scientific sense. Thank you, Mr. Chairman.

MR. BILLY: Ken. Myron.

MR. STOLTZFUS: Hello. My name is Myron Stoltzfus. I'm from Stoltzfus Meats in Lancaster County, Pennsylvania. We have a family owned meat business along with some other related businesses, including a small family restaurant and, unfortunately, a seven hundred -- -- hog operation if any of you are in the ag business you know what I'm talking about there.

On the appropriate short term measures, yes, I think short term measures are appropriate. There's been encouraging results from the microbial -- anti-microbial treatments and washes. There's some other short term measures that are probably already being done in the plant that are just classified as such. By the nature of this business some of a lot of what is being discussed is probably already being done. It's a matter perhaps of documentation and some of the details
that are the stickers.

My concern is that too much emphasis is possibly being placed on HACCP. I really don't believe that HACCP is going to be the silver bullet that it's intended to be and the reason I say that is because, to my knowledge, there hasn't been any extensive work done on exactly where most of the problem lies or where the problem lies. Perhaps it's easiest to think that because food inspection is in place in the meat industry that's a good place to start and that's, I think, where you've started with the near term measures. But to consider that and to consider what will follow as you implement all the details and to think that that will be a solve all situation here I think is a mistake. And I sort of have a question for you and it involves the near term measures. What else is being done in the near term in all segments of the food industry? I think it's unfair to single out an industry that probably already has been the highest regulated in the whole food chain. It's probably the strongest link in the whole food chain as solving our problem. Until that can be established to consider what area the food industry is, the highest risk, we may be wasting a lot of time and valuable time and energy addressing the areas that need to be addressed. There are -- we all know there's segments in the food chain now that have currently little or no inspection at all and there are areas that the ball gets dropped on and transportation -- I served some of the food industry. As I said, we're in the restaurant business and even struggle with employees at times understanding the food business and I know there's people that probably operate restaurants that maybe know how to make a steak but really don't know much about the food industry, don't know much about temperatures,
maintaining quality control because when the product's delivered to
the consumer in that situation you only see the finished product. You
really don't see the state that it was in and so there's a whole area
here that I think needs to be addressed and I think if FSIS banks or
invests all of its capital in this one area right up front, assuming the
wholesale changes in this industry will solve the long lay, yeah --
you know -- there will be increases but will it be enough for the
American public? Probably not when the first instance pops up. And
then I think it will only contribute to the cynicism that's out there in
the American public already and -- you know -- I would go as far as
to say that people probably trust their corner butcher further than
anyone on this issue right now and so I think that we -- you would
need to identify -- and correct me if I'm wrong -- that's why I'm
asking the question -- identify its weakest link, go after it. It's like
fighting a fire. Go to the source of the fire and address it where the
problem lies and wait to act in a wholesale way until you know
exactly where you stand on that.

MR. BILLY: Mike may want to respond.

MR. TAYLOR: Your point obviously is very well taken that I
indicated a little earlier -- I mean we will not achieve our food
safety goal if we don't address the points throughout the chain where
hazards arise and where interventions can be made to reduce risk and
there are gaps in our overall system of food protection obviously that
outside of the plants that need attention. And we outline some of
those in the preamble to the proposed rules to signal where we're
going in terms of addressing the broad spectrum and we do seriously
need to address these. It includes, in our view, and we're working
with FDA on this, a need to determine whether there should be standards -- some basic performance standards if you will -- that will insure the safety of product during transportation. I mean there are currently no national standards with regard to such basic matters as preventing growth during transportation and that's a gap in the system. We've got efforts underway to develop and need to work very carefully with -- you know -- the outside communities to address that. No question about it. And we also -- I mean down the chain. We're grappling with how and, again, working with the states and FDA on this, how to beef up the HACCP oriented approaches that could be observed at the retail level to insure food to improve the way products are handled there. So I mean there's no disagreement at all that there are significant challenges outside the plant environment. I think -- I mean our view is that we need to be working on all of those areas in parallel with this initiative. We have to recognize though the tools available to a federal regulatory agency are just necessitate differing approaches at differing stages along the way. And there's no question that we have a statutory charge from the Congress that explains why we are focusing the amount of resource we are focusing on the in-plant environment. Even so -- I mean even within that mandate we know we need to broaden our horizon. And so we -- again, as we proceed with the HACCP rule making and the efforts to implement HACCP within plants we intend to address the other areas. If you can obtain a set of top to bottom preliminary reports you will see a number of those reports laying out ideas to address exactly the question you're asking in terms of how we allocate our resources outside the plants as well as within them and
we just wholeheartedly agree with the need to do that and we're
investing effort to do it.

MR. BILLY: Okay. Steve Krut.

MR. KRUT: Steve Krut with the American Association of Meat
Processors. I think earlier Katherine asked a question -- you know --
we've been nine years down the road -- ten years down the road since
recommendations were made and this is the rationale or the
justification for doing something more immediately. I think there's
controversy whether HACCP could be implemented over three or five
or eight years or whatever segment certain portions of the industry
might take. But I think a lot of the suggested near term interventions
and strategies are still very controversial and, as I say, Dane made
the point very, very, very strongly that many of them are not
necessarily in agreement from the scientific aspects. Some feel
some aspects of this near term intervention are economically
unachievable particularly maybe with the regard to the refrigeration
requirements, maybe the infrastructure within the industry does not
even allow it. I would look at what areas we could focus on that
would be most meaningful and I would like to suggest that as a near
term initiative that the training in HACCP be moved forward as a
number one priority. I would like to suggest as well that the HACCP
training be expanded a bit more than maybe just HACCP principles and
deal with sanitation -- basic sanitation and basic microbiology. I
think that is a basic training that I think really does something to
improve our safety net. It is very compatible with other areas in the
food chain, be it retail or transportation, what have you. If you look
at the thousand plant review over the last year -- year and a half --
more than -- what -- fifty three -- fifty six percent of the problems
dealt with sanitation. And, as I say, I think we owe our American
public something more immediate than a three or five or eight year
wait and I'd like to see us move particularly with the training
emphasizing sanitation as well as the microbiology and the basic
understanding in those areas.

MR. BILLY: Nancy.

MS. DONLEY: I'm Nancy Donley from Chicago. I'm a real estate
broker. I'm also might be considered by some people in this room as a
child killer. My son died two years ago from E. Coli 015787 poisoning.
I just would like to go on record as saying that consumers should not
be the first critical control point in the system and that we have been
accused too long as being the killers of our own children.

Back to near term measures. I am a member of STOP -- Safe
Tables Are Our Priority -- and became a member of that after the
death of my child. The SOP's I think are just so doggone basic that if
I'm absolutely amazed that we aren't doing some of these things that
are being proposed -- that they aren't already mandated. I speak
specifically about pre-production microbial testing verifying
sanitation -- basic sanitation in the plants. Hand washing and knife
disinfecting between each carcass and skinning and evisceration and
just washing the cattle prior to slaughter. STOP feels that these are,
as I said, very basic and should be mandated.

STOP's position on anti-microbial treatments -- we do not feel
it should be mandated; that microbial treatments emphasize post-
contamination clean-up rather than in-process control measures.
They should put also exacerbate the problem by causing very small
particles to become embedded in the meat and spread further.

Cooling requirements are fine. We agree with Mr. Taylor that there is -- it's fine to have these temperature requirements but there is a problem that once the meat does indeed go into transit that we do have a weak link there and that there's something needed to insure that once it leaves the facilities that it gets -- it gets put into -- it maintains the same temperature along the route.

MR. BILLY: Finished?

MS. DONLEY: Yes.

MR. BILLY: Caroline.

MS. DEWAAL: I'm Caroline Smith Dewaal, Center for Science and the Public Interest. I want to just respond to a couple of remarks I've heard today on the command and control aspects of the near term initiatives.

I think there are some food safety requirements which are fairly basic. Sanitation and temperature controls sound like two standards which should be basic and fairly uniform across the industry. I'll be interested when we get to those, Dave, to hear the discussion on those sections. But I think that there is a role for a regulatory standard for things which are basic to provide a level playing field for the industry. Otherwise, enforcement is going to be done by every individual inspector in those plants and we can't just -- it doesn't work to guaranty uniformity. So I think that there -- I hear a lot of discussion about command and control and we have to move away from it but for things which are basic and which are uniform it may actually work against the industry and against the need for some basic uniformity and some standards you can rely on. To be saying,
oh, we don't want anything that's command and control, I don't like
the term command and control. There are appropriate regulatory
mandates and I think that's what we need in this discussion to figure
out what those are rather than having a knee jerk reaction against
anything which is mandated. I'm done.

MR. BILLY: Other -- does anyone in industry or anyone else have
a comment about what Caroline just said in terms of a distinction
there between some basic requirements?

Irwin, are you on that? Okay.

MR. MOSS: I did pose the question at the March round table or
whatever they had at Crystal City at the end of it regarding the
sanitation problems that were found during the surprise inspections.
The question that I asked -- I asked the USDA do you feel that the
deficiencies were the results of inadequate regulations currently on
the books? The USDA came back and answered that, no, we don't feel
that. There are currently adequate regulations on the books to
guaranty sanitation in the plants every day. I own a USDA plant in
Cincinnati, Ohio and I -- I know the USDA regulations and there are
adequate regulations today currently on the books to insure properly
sanitized and proper sanitation in plants.

MR. BILLY: Irwin?

MR. MUSKAT: I'm Irwin Muskat, President, Jack Pack Foods.
We're a portion plant, approximately five hundred people. We've been
in HACCP, maybe a less formally designed form of HACCP than we are
currently in now, but we've been in it for ten years.

As far as near term measures are concerned, I only wish to
address that issue right now. I'd like to go into other issues later.
But of the four near term measures -- the micros, SOP's, intervention, and time temperature requirements -- these are all extremely important issues. There's no doubt that the industry has to address all four of those issues. However, for anyone to mandate them would be so counter productive to the overall program for HACCP that you would -- you'd certainly bury yourselves in bureaucracy and controls that were and will be totally hard to control, ineffective in the overall program, that I think instead we should be looking at those four near term measures and aiming them toward our overall goal. Our overall goal is to -- and I hear it loud and clear -- is to get into HACCP programs. If we can develop the bases of these HACCP programs by mandating rather than the four near term initiatives or measures but mandate that we all start incorporating those four in pilot HACCP programs within the industry, within each plan specific to plants, I think we will gain a lot more stature. We will gain a lot more initiatives into improving the speed with which we can all get into HACCP programs.

We currently have nine HACCP programs within our small company because we have nine specific processes. Those nine specific processes as far as bacteriologicals, guidelines, and standards are concerned require several different sets depending upon what we're working on. If it's raw materials coming in the door that's fairly standard for most product. But as far as any other facet of our operations are concerned it will vary immensely in the level of bacteria that we would expect to see if we were in good control. They will be aimed at different types of bacteria depending upon what we are accomplishing in that process, whether it's a cooking process
or raw process. If it's in our cooking building we'll be looking for
salmonella and listeria a lot more strongly than we will in other
areas. We'll be looking more for our standard plate counts and our
cola forms to show that we're in control. Now, I'm not talking about
pathogens. I'm talking about measuring how well we're controlling
our process and that's what HACCP is designed to do. Are we in
control, are we doing what we say we're doing? If we can gear all of
these efforts toward garnering a consensus to an industry,
government, and the professionals that we have here -- I notice there
are people that represent some of the laboratories that have done an
immense amount of work in our industry -- if we can get these people
together and determine some guidelines -- guidelines -- not
standards but guidelines under which most plants can develop proper
programs I think that we will be far better off than mandating
anything. The same is going to be true with time temperature, SOP's
for sanitation. I can't believe that there's anyone in the industry that
doesn't have either informal or formal SOP's for sanitation if they
want to maintain any assemblance of good product going to the
customer. I don't think there's anybody in the room that's in the
industry that wouldn't be willing to have formalized SOP's for their
sanitation procedure provided that they have the means by which they
develop those SOP's that is plant specific and process specific. Sure,
there are certain general characteristics of those SOP's that have to
be standardized and should be standardized but you still have to have
a very definite program that will be differentiated by where you are
in your facility, what you're doing in the facility, and how you want to
develop your overall HACCP program.
As far as interventions are concerned I can't address that personally. We're not in that part of the business but I think that given the opportunity I think industry will come up with interventions that probably will be far better than anything that we could promulgate by law today. Thank you.

MR. BILLY: Pat --

MR. MUSKAT: One other thing I might mention. Sorry. Whenever you're doing any of this, whether you want to set up guidelines or you want to hopefully not set up standards it isn't the guidelines and it isn't the standards going to make or break you, it's your trend. And unless you have a trend analysis in your HACCP programs and you monitor those trends to see that you're in control and you're improving rather than losing it then you might as well not even have the program.

MR. BILLY: I have Dell, Bob, Joe, Rich, and Carole on my list.

MS. MACKLOW: I was going to address Caroline's specific point about standard and it might be helpful to understand a little bit about the difference. I heard Kim Rice talk about making hot bone sausage. The kinds of things that happen in making hot bone sausage and the kinds of measures and microbiological sampling and so on making that will be vastly different than somebody that goes and buys either frozen or deep chilled pork trimmings and makes sausage from that kind of product. We cannot make a one size fits all for the different kinds of processes like that. So that may help you to understand that's just a very minor example but it goes on over and over again because this is a very complex industry.

MR. BILLY: On this point?
MR. GILBERT: Rich Gilbert with the American Public Health Association. And just to let you know twenty years ago we filed the suit APHA against Butts that probably could have dealt with a lot of food safety issues -- the adulterants and pathogens and it was thrown out of court. But my major concern and one of the few things I've agreed with you, Rosemary, this morning and I didn't agree with that comment that children and the fast food industry that didn't -- they didn't -- they ate food that was not cooked properly. That's, I think, others are to blame than that and I think that was not properly our position and it may be your position. But, Irwin, I think I agree with you. The American Public Health Association would say that and also public health professionals in general, CDC would support the concept that establishment specific HACCP, i.e, one size does not fit all. Plants to be developed and reviewed and delegated on a continuing basis by not only your establishment but government FSIS personnel. But we believe certain minimum core standards for such things as time and temperature requirements should be mandated for all HACCP plants. These core standards could be co-developed by FSIS and industry representatives.

MR. BILLY: On this point?

MS. SIEMENS: Angie Siemens with Oscar Meyer. I'd like to address Caroline's specific question on I think we've got a problem with some definitions of what we consider command and control. In our viewpoint, command and control and what we see in applying these to the near term initiatives we could also use the word prescriptive without flexibility and that's where I see command and control and our definition. We use anti-microbial treatments in our
processes. We have two different turkey facilities. We do not use
the same process in both facilities because we have different
equipment, we have different raw products that come into those
facilities. What we are seeing is going back to a statement that Mr.
Taylor made. He was looking to codify a single effective treatment.
That is the problem that we have with the current command and
control. There is not a single effective or several effective as the
regulation came through that was very specific in a very -- you know
-- three or four types of treatments that we would be allowed to use
under the current proposal. We use chlorine in our chillers as our
treatment and we feel that that is very effective in our processing to
control and meet the same goal that you're headed to but it's not in
the regulations nor is there a flexibility for that type of treatment in
addition to other technologies that could be available. That's what
we disagree with in terms of command and control were we not given
flexibility to fit various treatments to our processes to achieve the
ultimate goal of safe products that we have.

MR. BILLY: Mike.

MR. TAYLOR: Let me just clarify what I was meaning to say
about what we proposed. It was not to mandate a specific anti-
microbial treatment but to say that the proposal was that plants
should have one effective anti-microbial treatment. In the proposal
identified some that are based on data we've got and believe to meet
some standard of effectiveness but the idea was to -- we're talking
about the idea that we had in mind was that the standard -- the
requirement would be to have an effective anti-microbial treatment
and -- and I think we hypothesized as that meaning effective for a
one log reduction but then it would be -- we would be any -- any
treatment that met that standard would meet the requirement. We
had simply, based on what we knew, identified several that we
believed met that standard.

MS. SIEMENS: It's just that -- Angie Siemens, Oscar Meyer. The
one thing that we felt the language is not clear enough to say that we
have alternatives and that's where our concern is on some of -- you
know -- not with those very specific if they can show a one log
reduction relative to the actual language proposed.

MR. TAYLOR: Suppose we change the language and did that. What
effect would that have on your position? Suppose we just said have
one treatment that accomplishes a one log reduction.

MS. SIEMENS: I'd be very careful. I'm not speaking for the entire
industry. There would be some people who would disagree. I think
that there are some considerations that we would have that I have
some problems with saying one log reduction because I think there
have been several scientific people who have said okay, let's have a
hurdle concept. If we can approach that with several different
treatments you're still reaching the same end point. So I have a
problem with saying one treatment only has to meet the hurdle. So I
think, again, there are some devils in the details of which we'll get to
when we get into talking about anti-microbial treatments but I think
the key point is here we want flexibility and the proposal does not
offer some of that flexibility and, again, I think we'd be more
prepared to address that as we get into the specific topic.

MR. TAYLOR: You know -- it's very good that we got a chunk of
time set aside on this issue just as a sort of signal of where our
current thinking is. We are not the least bit wed to the specifics -- you know -- as written in the proposal. On this particular issue, we think as a general matter, is desirable as I think most people in the room agree, it's desirable for folks to be taking steps that are available now to take to reduce pathogens and -- you know -- we are completely open -- you know -- as to the manner in which we accomplish that and I think the session we've got on anti-microbial treatments is an opportunity to talk about that and what kind of flexibility is appropriate, what the appropriate linkage is to some -- you know -- more pure performance standard, but it's the objective that I think we're going to keep our eye on and I think not to get on that particular issue, we are not the least bit wed to the details of what was in the Register. We ought to be talking more when we get to the subject. I mean that's -- let's talk about what the possibilities are.

MS. HANNIGAN: Katie Hannigan with Farmland Foods. I have a question, Mr. Taylor. When you're talking about the anti-microbial spray, are you talking a one log reduction in general micro flora or pathogen?

MR. TAYLOR: We have a whole array of incredibly expert people from the agency, including Pat Stolfa who will deal with that.

MS. STOLFA: I don't think that the proposal was specific on that that the preamble talks about the concept of something that could be added to -- we have kind of a list of anti-microbial treatments that historically we have approved and in order to give some idea of what it would take to be on that list we discussed the concept of log reduction but I don't think we went beyond that. Certainly that's --
you know -- that's a detail that makes a lot of difference.

MS. HANNIGAN: Is it pathogen or just general flora? I mean if we go ahead and we are mandated to put in the anti-microbial spray and if we're talking pathogens and you do not have a one log reduction because there's not enough there to start with what was the purpose? I guess I want clarification if you're talking pathogens or just total count or exactly what -- you know -- what you're basing your decisions on that we need this across the board.

MR. MORRIS: Glenn Morris, FSIS. I think in part the answer there is not necessarily an answer to your question and one of the things we would want to discuss would be the appropriate approaches in terms of development of a performance based standard. I can tell you that obviously ultimately the goal is to reduce pathogens. The question is whether we can integrate a process control system -- you know -- have a process control system which in turn will give us what we want ultimately in terms of pathogen reduction. But I think this is one of the issues that we need to deal with and, again, I'm not sure that that has been that clearly formulated at this point in time.

MR. BILLY: Okay.

MR. JAN: Lee Jan with Texas Department of Health and representing NASDA. I agree with the last comment or two. One log reduction from what and if we are looking at anti-microbial spray to reduce and we know where we want to get to and if that happens to be a one log reduction then I think that mandating anti-microbial treatments to get there when someone's other -- someone else's other process may already be there is where we're getting too much command and control. I mean there may be -- you may not need -- if
we have some standard and that's the problem. If you're saying you're
gothing to change the wording to satisfy Oscar Meyer so that they can
use whatever treatment they want but you're still saying they have to
have a treatment why not change the wording where you can use a
treatment and allow and authorize and don't get in the way of
treatments but don't say you have to use a treatment. I have concerns
that number one, ineffectively applying treatment may add bacteria
or use of the wrong equipment or add residues or you may have a
contaminant just like -- lot more -- when you start adding you have
chances of adding stuff that you don't want to have remaining on a
carcass. Also, we've seen reports of where adding some sprays may
actually increase the survivability of the pathogens. So there are
things I'm not real comfortable about mandating something that might
lead to be a problem but I would also not want to stand in your way so
that would be -- that would be where I might see the changes -- you
know -- look for a target to get to but don't say exactly how to get
there. Thank you.

MR. BILLY: Dell.

MR. ALLEN: Dell Allen with Excell Corporation, Wichita, Kansas,
in charge of quality assurance and other things.

I had a long career in academia before coming to Excell and I've
had a lifetime in Excell. I would like to establish my credit
credentials though in the job that I do in charge of food safety. I'd
like to say that I share with Nancy here a common background. I lost
a son and a mother to a drunk driver. And in the job that I do I want
to create no one that kind of pain. I have direct line responsibility
for our food safety program through our plants and I will fire, I
assure you, anybody that violates our rules and regulations and I have
that authority.

The only thing I would like to tell Nancy, I would love to be able
to tell her that I'm never going to endanger another child with E. Coli
015787. I cannot do that. It's much like being in the middle of a
Kansas thunderstorm and knowing that lightening is going to strike
somewhere but trying to be able to predict where it's going to strike.
That's about how effective we are at knowing where that organism is
or where it will show up. If we do a test and find that that product is
clear the only thing that I know is that one small sample that I tested
is clear. There's a ninety nine percent probability that it could still
be in the load that I tested. That's how ineffectual our science is in
this whole area right now. Specifically, to near term treatments,
acid based rinses, we've got several problems with them. Number
one, all bacteria are not bad, believe it or not. We threw out three to
four years ago tested lactic acid rinse in our Dodge City plant and it
proved very effective at reducing micro flora on carcasses. Well, in
the one log to better range so we started using it. Had approval to
test it and use it. We were going along in great shape and all of a
sudden for every action there is a reaction I'm told and sure enough it
happened. We created a whole different problem in our plant -- the
environment. All of a sudden we had gas blow ups in bags. We had
spoiled beef in bags and what we had done, we had removed the
competitive micro flora from our carcasses to the extent that
Lactobacillus grew rampant in the cooler environment. So we had a
tremendous problem. The only way I would use an acid based rinse is
if I could follow it with a chlorine rinse. I can't do that because we
have to export to Canada and our people that buy from us, like Oscar Meyer that make lunch meat and all that, they have to export to Canada. You can't export to Canada if you hyper-chlorinate your water. Hyper-chlorination in Canadian terms is more five parts per million. So it's an effectively -- you know -- it just doesn't work. We cannot -- and there are other countries that have other restrictions on export product. We don't know when carcasses are going through the slaughter floor which parts we're going to export or which carcasses we're going to export. We can't segment them. The export market, believe it or not folks, is a tremendously important market to the domestic livestock industry in this country. We've had a wreck in prices this year and a lot of people are in trouble who would have been in much greater trouble without that export market. So that's another obstacle that we have to mandated, if you will, prescribed anti-microbial treatment.

So, again, I get back to the point that others have made. I think it is a case by case basis. It has to be addressed on a situation by situation basis in those type things. It is really no more than an effective part of an individual process controlled mechanism in an individual plant and they need to address what that is and FSIS needs to provide the flexibility to look at each one on a case by case basis and work with them.

MS. DONLEY: Tom -- Mr. Chairman, may I respond?

MR. BILLY: Sure.

MS. DONLEY: I just want to say that consumers -- I appreciate your condolences and my condolences to you and your loss -- consumers are a lot more savvy than given a lot of credit for. We do
not expect guarantees in anything in life. What we do expect is that everything possible is being done before it gets into our hands, into our supermarkets, and into our restaurants. Do we have a responsibility? Yes. Once it's into our hands and once it's to the restaurants and other establishments have a responsibility? Yes. We're looking at farm to table chain of responsibilities but right now not everything is being done to make sure that it is in the best possible condition by the time it gets to us and, as I said before, it is unfair of industry to make consumers be the first critical control point in a system at the very end of the chain. That's the point I want to make.

MR. ALLEN: I absolutely think that's going on now, Nancy.

MS. DONLEY: No.

MR. ALLEN: The liability of any company in the social environment that we live in absolutely precludes that happening.

MS. DONLEY: We do not at this point in time have anything done. I'm going to speak specifically now for 0157. There is nothing being done except just very, very recently has the USDA started doing a random sampling for 0157. Five thousand tests, half of them in retail establishments, half of them in plant capacities. This is just something that's very, very, very recent.

Another point here is, if industry is going to take the position that consumers be responsible for the product then industry better darn well be getting out there and telling in no uncertain terms to consumers what it is they're dealing with because let me tell you, they don't know. And it is your product and you need to stand behind it and be responsible for it that if once it gets into the public's hands
there might be a problem. It should be spelled out loud and clear that
unless you take every single precaution that in handling this product
and that little tiny label doesn't cut it. But in no uncertain terms and
unless you cook this to death and say a prayer you are endangering the
lives of your children. And industry for obvious reasons has not
chosen to take that route in educating consumers.

MR. ALLEN: I'd just like to respond to one thing. In the past two
years, Nancy, my company has put on at least, I'd say, fifteen food
safety seminars in which we have had our major customer retailers
in those seminars and they heard the exact same message that I just
gave you. Every one of them. And that touched probably every major
retail chain in this country. I'd also like to tell you that in 1991 our
company was testing for 015787 to try to find out what the incidence
was of it, where we could identify it, if we could identify it. So I
think we've done much more maybe than the public is aware of.

MR. BILLY: Other comments on this specific point? Caroline?
On this?

MS. DEWAAL: I really want to respond to Katie Hannigan's
statements about command and control cause I think it's inaccurate.
On page 6790 in the Federal Register it says new anti-microbial
procedures, including variations on those listed below, will be
approved for use by FSIS to meet the proposed requirement for an
anti-microbial treatment provided data are submitted demonstrating
they are safe and effective for that purpose. Current interventions
generally provide at least a one order of magnitude, ninety percent
reduction in the numbers of bacteria of concern, which I believe
means pathogenic bacteria on treated carcasses. I don't see that as
command and control. I don't see this as prescriptive. I see that
language as encompassing what you were saying.

MR. BILLY: Jim? Patrick?

MR. BOYLE: Thank you very much, Mr. Billy. I'm Patrick Boyle
with the American Meat Institute and I would just briefly like to
comment upon some of the concerns and points that Mrs. Donley
raised. In terms of the responsibility industry or, in your mind, the
failure on the part of industry to make consumers aware that they too
are part of a comprehensive food safety chain. You, on a couple of
occasions, have made reference to the fact that it's unfair for
consumers to be first critical control point in a food safety chain.
You do have a role to play as consumers, and for raw product, whether
you're preparing it in a food service establishment or in your kitchen,
you are a critical control point, particularly for the pathogen E. Coli
015787, but for pathogens in general because for raw products to
date the only thermal step that we have available is cooking but there
are a number of other steps or critical control points that are
available to us well before the product reaches the retail store or the
food store or service establishment or the kitchen itself. A lot of
those steps have been researched and proposed and presented to FSIS
and many of them have been implemented over the last few years as
we become more aware of the risk associated with E. Coli 015787.
Since the outbreak in the Pacific Northwest, my organization as well
as a number of other specific companies and in cooperation with the
universities have conducted millions and millions of dollars of
research and we have developed intervention strategies that are
demonstrating to us our ability to reduce pathogens in general and
further reduce the incidence of 015787. Use of steam vacuum
technology, use of carcass rinses, either by themselves or in tandem
with other rinses. We're experimenting with the exposure of
carcasses to intense pulse light that reduces pathogens. They are
intervention strategies but they are not thermal steps that cooking
is. It is not a thermal step like irradiation is which is pending before
the FDA for approval for its use on beef. Until there is that thermal
step on raw products it is appropriate and indeed necessary for all of
us to be aware of our role as a critical control point and for cooking
as the final critical control point in that whole chain of farm to table
food safety. In order to better educate consumers there have been a
lot of efforts in that regard. The government itself has mandated
that the label that you refer to, and by itself, admittedly that may not
be enough but it's part of industry-wide education program, I think's
an important intervention strategy, if you will. Similarly, my
organization, in cooperation with retailers and food service
organizations, developed within a few short weeks after the Jack in
the Box incident in the Pacific Northwest more comprehensive safe
food handling brochures that have been reproduced and distributed in
retail stores throughout the country, all part of the educational
program. The FSIS hot line is part of that consumer education
program disseminating information about our responsibilities. But
HACCP itself is, while not a panacea, if we get it right and get it in
place will provide us with greater controls to reduce pathogens in
general and that's why it's so important that we move as quickly as
we can in that area. But to suggest that industry is not doing
everything it can is contrary to what we are actually doing in our
plants every day and to suggest that we are passing the buck, if you will, to the consumer as the first critical control point is not an accurate characterization of how we see our own role in the chain nor how we see the role of the ultimate food preparer in the chain.


MR. HAHN: Bob Hahn, Public Voice for Food and Health Policy. I can understand a lot of the specific concerns about each of the interim measures. What I still can't understand is the philosophical objection to the interim measures and I don't think a lot of consumers are going to understand it either. It seems to me these are not highly prescriptive with the exception of the time temperature requirements. The exact parameters of the time temperature requirements can be debated and unique situations can be given -- be granted waivers. But if these measures are basic to food safety I just don't understand what the philosophical objection to them is.

MR. BILLY: Al?

MR. OSER: Alan Oser from Hatfield Quality Meats. I've been dealing with USDA personnel now for about twenty five years in the plant in Washington and generally arguing with a lot of people back here over those years. The philosophical problem that we're facing now with these prescriptive regulations to understand it you have to realize that the -- we've come to a crossroad here. Up until the point that USDA began getting very serious about HACCP the industry controlled food safety by compliance to regulation. It's important to understand that. The FSIS dictated what food safety was through the issuance of regulations. In a HACCP system you define food safety through a hazard analysis which is an on-going process. The
regulations -- I'd only use the term don't count -- but they're immaterial to a certain extent. What is important is your hazard analysis and this is where these two things conflict and this is why we're having the problem with it. Let's get specific on carcass washes. The agency issues a regulation which is what this will be. You have to have a carcass wash. You put it in. That carcass wash represents the agency's view of how you get carcasses in a sanitary condition. Their stamp of approval is on it. We have presented in another USDA form -- I won't go into it in great detail -- a system that prevents contamination on carcasses. We have shown that to over time to give us a three log reduction in bacteria. Here's the problem. This is a competing technology. It has nothing to do with wash cabinets, nothing to do with stainless steel. If you're operating in a hazard program you have the prescriptive requirement that to satisfy this problem of contamination on carcasses you must have the carcass wash or you're not going to move to the other technology even though it may be out there. If, however, you come to because you have to have -- excuse me -- you've got to have a carcass wash -- have to have it -- it's there, it's in the regulations. If you come to the conclusion through a hazard analysis that the only way you can get your carcasses and be sure your carcasses have a low enough level of bacteria to satisfy whatever the standard is going to be, fine, you put it in. If another technology comes along that's better than that, fine, you take it out. If it's part of the regulations you're going to have to get a regulation polled. A lot of us can remember the last -- an administration that was quite busy in the 80's philosophically didn't happen to like the idea of publishing regulations period which meant
you couldn't be regulated because you had to publish a regulation to
get the other regulation out and one of the hardest things to do is to
remove a regulation which you're into, right? You can appreciate that
because that stuff can be horrendously misinterpreted that you're
dropping the ball at any point you try to repeal a reg. And this is
where we philosophically have a problem on this issue. We need to
decide which way we're going here. Are we going to define food
safety through regulation, or are we going to define food safety
through hazard analysis? They are different.

MR. BILLY: Joe. Carole.

MR. TAYLOR: Just in the spirit of conveying our current thinking
-- I mean just in response to what Alan said and looking specifically
at anti-microbial treatments but I would say across the board where
similar issues arise the last thing we want to do is codify in
regulations requirements that would prevent improvement in the
manner in which you just described the possibility that you could
write a mandate for a certain treatment intervention and in so doing
stymie beneficial innovation to move beyond that and so throughout
we're looking very hard to be sure we don't do that and, again, when
we get to the discussion of anti-microbial treatments specifically
we -- I mean we will focus very much on -- and if there is any role in
establishing sort of a basic standard of care with respect to reducing
pathogens near term how do you do that in a way that's sufficiently
performance standard oriented so that you don't stymie innovation. I
mean we need to come to grips with that.

MR. BILLY: Ron.

MR. PRUCHA: Mike, you know in my response to your -- I would
say don't do not mandate performance standards and by that I am
saying issue guidelines -- good manufacturing practices, whatever,
that the agency can live with. I know there are microbiological
guidelines for what is wholesome, edible, raw product at various
stages. The agency should put these out and these are the agency's
expectations and goals as to what you can do or should be attaining
for performance process control system that the industry must run.
But I think I can guarantee that say you put your forty degree carcass
temperature into effect, twenty four hours and five minutes after
that thing goes into effect I can about guarantee you that some
inspector will find a cooler full of carcasses at forty one degrees or
a trailer load at forty two degrees and then what are you going to do
with that type of product that essentially is edible, is it wholesome.
Are you going to have it condemned or go to dog food or rendered or
whatever? It did not meet the standard by some margin and I think
that is for all intents and purposes there is nothing wrong with that
type of product. You've got to come to grips with something like that
because -- you know -- if you put those types of standards out there
-- the prescriptive types of standards -- and the inspectors will
absolutely go by them and there is no -- without -- you know --
without a whole lot -- they won't be able to exercise a whole lot of
judgment in those -- in making decisions and you're absolutely going
to have tons and tons of meat in retained and on hold and whatever
and I think by the use of guidelines and goals that the industry can be
expected to meet you'd be in a much better position to control those
processes then by a very tight standard.

MR. BILLY: I have Jim and Dane and Carole. So, Jim.
MR. LOCHNER: You got a question for me?

MR. BILLY: Dane?

MR. BERNARD: Thank you Mr. Chairman. Dane Bernard, National Food Processors Association. I listened with interest to the last segment of this debate. The philosophical difference that was talked about earlier I think Alan Oser put it very succinctly as to where that leads us. Let me make clear as was made clear in our comments, we are certainly not against baseline criteria. The National Food Processors Association nor any other reputable organization is going to go out and say there should be standard operating procedures on sanitation. There should be. We support that. And we're not replacing throwing out everything that's in existence now, a point that Mr. Gilbert made earlier. There are elements of existing regulations which are very compatible with HACCP and would be rolled right in -- the cooking guidelines on roast beef, cooking guidelines on chicken. A lot of things will roll right in here so we're not throwing everything out. We're not starting fresh with HACCP. There is a concept that the Canadians labeled prerequisite programs and I think that is our concept of where you begin. There should be solid programs in place supported by appropriate rules that mandate good manufacturing process and they are already there to a certain extent and if they're not then we need to fix those holes if there are holes. But when we say we're going to take up HACCP and build on the safety record that we have and make it better and we're going to utilize HACCP, as I've said before, then we begin to look at everything with a light as to how to support that. There are elements of the interim measures that were proposed that possibly should be, if not
adequately treated in separate regulation, should be done so, but
those which are more nebulous in terms of the science behind them
and the broad implications and I think if it's been said -- you know --
nobody here that I've heard supports every element in every operation
of what was proposed in the interim measures. So I think if I could
lend my own impression to this, if we decide at the end of the day
that the agency needs to mandate interim measures definitely there
should be sunset when we hit HACCP. Those which form those
baseline programs, the prerequisite programs should be dealt with as
such and should be the place we start and the foundation upon which
we build our HACCP program. Thank you, Mr. Chairman.

MR. BILLY: Carol?

MS. FOREMAN: Thank you. I'm Carol Tucker Foreman. I served as
Assistant Secretary for -- with responsibility for meat and poultry
inspection from 1977 to '81. I would really have preferred to hold my
comments until we began discussing performance standards. It might
have eased this discussion we're having now had we started the
discussion with performance standards because I think some people -
- Angie, Dane, Alan Oser -- have made some good points about that --
about the difficulties with some of the interim proposals. On the
other hand, the objective of the meat and poultry inspection program
is food safety. It is to provide a safe product to the American public,
the safest possible product to the American public and for that the
taxpayers spend six hundred million dollars a year and in return the
industry gets a little stamp that says to the public your government
has examined this product and says that it meets their requirements.
That's a very serious obligation. With all due respect, it's more
serious in my mind than that that goes along with your label on it, Mr. Dryden, because although your label clearly connotes quality that is not true across the board and a lot of products are sold without labels and it is that government label on there that says to the public this meets a standard. I'm in favor of HACCP but Dane and I have had this discussion over a long period of time. HACCP, once it becomes part of a government regulatory program is not the HACCP that you have in your plant. If you want to have HACCP with no performance standards then in my mind it can't be part of this government program. If the government is going to have the inspector put a stamp on it that says this product meets the public's standard for safety then you have to have a performance standard attached to your HACCP program. It stops being quality control to meet your needs for process control of meat the plants need and becomes therefore part of the public's need to protect human health and that requires some sort of performance standard in the end. I would be prepared to forego specifics on some of these interim measures if there were a way to initiate performance standards at the end of the line in their place.

MR. BILLY: Rebecca.

MS. HOLLAND: Okay. I'm Rebecca Holland from Kansas City, Missouri. I'm a processing inspector. I've been in the food inspection for seventeen years and many of you -- listening to you I wish I was working in your plant every day. You care. The ones that we have the problem with are those maybe other twenty six plus thousand we have right now. We're short staffed. We have up to twelve plants a day. We may do pre-op. This plant may have a QC program. Okay. They're taking care of themselves so okay, I won't go there. I won't have to do
pre-op this week. Okay. I go next Wednesday. And it takes him two
and a half hours to get the place cleaned up to operate. Those are the
things that we're concerned about when if you -- you know -- we feel
that these other plants take care of themselves and it's something
that we see every day. Granted, the majority of -- I'd invite any of
you to Kansas City anytime. We have great barbecue there. But in the
majority care, they do run a good program but we need to -- the
HACCP concept is good but we need to intertwine with what we've
got. We can't give up. You just can't throw everything out. You've got
to put it together and I just want to comment on -- you know -- the
forty degree. You have a guideline. We have some common sense. You
know -- we don't have to put it in dog food. I'd like to comment later
if I could. Thank you.

MR. BILLY: Tom.

MR. DEVINE: -- -- (microphone not working)

MR. BILLY: Rosemary?

MS. MACKLOW: I think Inspector Holland made a valuable
contribution that would be worth looking a little behind what she told
us because it may help us to understand how the system now either
works or fails us. She said that she -- you know -- went in and it
took them two and a half hours to fix the place up and that they were
a company where they can QC program. In my experience, a company
with a QC program like that, we'd have a sanitation program and there
-- depending on how large or small they were their foreman might
have gone through his standard operating procedure checklist to look
at the kinds of things that she was looking at. Maybe the general
manager does this once in a while and yet the day she was in it took
them two and half hours to fix it up. I wonder if she could tell us what kind of action she took to make sure that they don't just clean up every two weeks again; that they do it on an on-going every day basis; that if they've got a QC program they are held accountable to meeting that and does she go and look at their records and say now I found this machine unacceptable, but you looked at it every day for a week and a half and you found it acceptable. Now I'm going to hold you to my standard which is that there be no bits of fat or no smears or whatever it may be. I wonder if she could give us a little bit behind that one cause I think it would be useful to better understand where those responsibilities lie.

MS. HOLLAND: Okay. Thank you, Rosemary. Since then -- okay -- with that course the -- the department was tagged -- the plant was tagged off. They proceed to clean with cold water. The QC -- the lady that was in charge of QC said well, we're ready. I go out and I checked it again. And I said, I'm sorry, you're not ready. I talked to the manager. I asked him why his program wasn't working. Well, the sanitation group that we've got in here cleaning, they're just not doing their job. And then I asked him if this -- you know -- what would they have done had I not been there that morning. And, Rosemary, I didn't get an answer. Since that time though we have increased the pre-op sanitation. This is a processing plant. We have increased the sanitation. They have changed their -- you know -- as often as we do the pre-op we've increased that or we did that for about -- for a certain length of time. They started -- the plant manager starting giving the QC person more authority and they can clean up with hot water in the morning. There's -- then we have --
when we went back in to recheck this program they have -- they have
straightened it up and like I say they have changed their sanitation
people that they have coming in at night to do the clean up. So does
that answer your question?

MS. MACKLOW: Yeah. But did you go and look at some of their
records? I mean everyone around this room is in the industry and
knows that you do pre-op sanitation every morning. I mean somebody
does it. If the USDA person doesn't do it somebody in the industry
does it. I mean it is a requirement before a plant starts operating.
We've got to keep some kind of checklist. Do they have that kind of
thing? The deficiencies did not show up on their checklist. So you
showed them when your deficiencies were and where they may have
been finding them.

MS. HOLLAND: That's right.

MS. MACKLOW: Okay. How did they know since then learn from
the error of their ways? Have you gone back and looked at their
records and their note-finding deficiencies cause they didn't know
what a deficiency looked like?

MS. HOLLAND: I think they know what a deficiency looks like but
their record keeping is not what it should be.

MS. MACKLOW: Okay. What have you done to make sure their
record keeping improves?

MS. HOLLAND: There's -- okay -- I was a relief inspector in that
plant but the other inspectors have checked -- you know -- and tried
to talk to the management. They have -- went over their QC program
with them and -- but we still can't go in there every morning. We
don't have the manpower.
MS. MACKLOW: You shouldn't have to.

MS. HOLLAND: That's right.

MS. MACKLOW: But you've now identified another critical area or failure which is very germane to the discussion around this table and that is that not all inspectors see the world alike and you had an inspector in there, and it may come as a surprise to Mike Taylor, but it's not a big surprise to me that they don't all see the same things and, again, they need to have very clear performance guides. I mean it's what happens all the time with reviews and everything else. We go through it every day. And it's -- the reason I'm here today is to say, okay, how are we going to improve this system so that when you go into a plant maybe once every two weeks that you can be sure that everybody else in your program has used the same measuring device. We're right back to where we started this morning.

MR. BILLY: I think there's an inspector -- would you identify yourself?

MR. WATSON: I'm Clarence Watson from San Diego. I'm an inspector. I've been an inspector for fourteen years and just to support what she's saying, there are a lot of plants as TGC and what we call they pencil whip you with their documentation. Now we do pre-op sanitation on a daily basis but they are random samples so the plant does not know where you're going to come in. The total quality control plant -- when we go to that plant our first notification to plant manager is that we're going to do a pre-op, are you ready, and when they respond yes, then we go. We look at their documentation. We find out there's everything acceptable. But when you get to the plant we are finding other things. We're finding rusty equipment,
Plant maintenance is not being right so we are seeing that industry is not living up to their responsibility. Now there are directives to take this plant out of total quality control if they're not performing and it's called progressive enforcement. Now when we document repeated deficiencies then we are documenting -- we write speed memos to our circuit supervisors to inform him that this plant is out of compliance, they're not living up to their responsibility. That's our only way to get them out of that total quality control system. Now that system and the plant likes the system because it has the emblem and it's a special emblem to the public. That means they are above USDA requirements. But it's that inspector's job in the plant. He's the eyes and ears of the public and if you're going to couple that with HACCP that inspector has been in there daily because what we're finding they're just pencil whipping us to death and it's not going to work. We are there for consumer protection. That's our job. Thank you.

MR. BILLY: Irwin?

MR. MUSKAT: I'm Irwin Muskat, Jack Pack Foods. I think we're back again to what is it we want to achieve here. If you want to set up standards all over again and double and triple the number of policemen that we're going to need to enforce those standards then we're going to be back to where we were, where we are, and further that even more mired in the same type of policies that we're enforcing on the industry today. If the end result is to have clean meat going out the door and safe product going to the consumer what you want to be measuring is what were the results of the plant's sanitation program, what did they factually tell you and what trend
analysis is available to show whether they are improving their status or not. You have factual information available to you through the technologies that are available to us today. If you're going to use that factual technology that's going to measure how well you're doing and the government is going to be able to come in and verify that your numbers are, in fact, what you say they are, then you do not have an honor system as was alluded to before. You have a system that is documented and verifiable by the overseeing Department of Agriculture to make sure that you're doing your job as you stated you would do it. If you're not, then you have to impose rules and regulations that will enforce you to either do your job or you don't belong in the business.

MR. BILLY: Dennis?

MR. JOHNSON: I'm Dennis Johnson, Olson, Frank, and Weda. I'd kind of like to follow up on Carol Tucker Foreman's point cause I've been hearing it from the industry as well is that it seems to me that if we're looking at command and control we're saying this is how you do this. If we're looking at HACCP we're saying you will provide -- you will control and have a performance standard benchmark at the end and Carol had indicated, if I got it right, that she would be willing to forego specifics if we go to performance standards at the end.

Actually, I guess I have two questions for you all, is, one, have you considered the use of performance standards rather than any of the interim measures or all the interim measures, and, two, if you have or even if you haven't what is a performance standard in your book? I mean I know what it means to me. Ron Prucha used it a little differently than I would but I would be really interested to hear what
a performance standard means to the agency, as least under current thinking. Thank you.

MR. BILLY: Thank you.

MR. TAYLOR: Performance standards can play various roles and I think it's pretty clear from the discussion here that we think that performance standards have a very critical role to play and I think you can look at them both in the context of alternatives to, for example, prescribing time and temperature for carcass cooling. We certainly do want to consider whether there's a performance standard alternative to that. Everybody agrees we need to prevent growth. Is there a performance standard alternative to mandating certain time and temperature requirements so we want to consider performance standards in that context. We mentioned earlier -- I mean if there's a role for government in establishing a standard of care for reducing pathogens on carcasses in a slaughter operation we certainly would want to consider a performance standard alternative there.

Performance standards also have a broader role though and, again, as I mentioned earlier, we'll have a whole -- I mean all of Friday is on this subject. There needs to be, in our view, a performance standard to serve as a measure of accountability for controlling and reducing pathogens that deals very directly with the issue of what's an acceptable level of food safety performance when it comes to reducing pathogens on raw meat and poultry products because that, having some measure of accountability for that, is what gives power, in our view, to HACCP as a systematic science-based way to control processes in order to meet an appropriate standard of performance, so we see a critical role for performance standards and,
in particular, when we complete the transition to HACCP it seems essential to the integrity of that and to the effectiveness of it as a tool for improving food safety to be some standard of performance for harmful bacteria on raw product.

#3 MR. JOHNSON: If I could follow up. I'm going to put words I'm thinking in Carol's mouth then I apologize. I think she was referring to, in effect, an end product standard as opposed to the individual performance. I don't know if she was or wasn't.

   Hi, Carol.

   MS. FOREMAN: I was.

   MR. JOHNSON: That's what I thought. Would you -- have you considered or would you consider dropping any interim measure in return for a trend analysis, finished product standard, what have you?

   MS. FOREMAN: I want more than trend analysis.

   MR. JOHNSON: Carol wants more than trend analysis. I probably am going to have a few clients kicking me under the table for what I've said already.

   MR. TAYLOR: We have chunks of time set aside for discussing each of these near term interventions and we're very open to discussing alternative ways to achieve the objectives of improving the safety of products. And I think we ought to, in the case of each one of these, we ought to have a focused discussion if what the practical alternatives are to -- to what we propose so I mean -- we hope that will be a very open discussion. I mean everything in the proposal is a very legitimately open for debate and that's what we're here for.

   MS. FOREMAN: Tom, can I -- this is Carol Tucker Foreman again.
Mike, you raised the notion of clearly in order to get to HACCP throughout the industry there's a period of time involved and we have to do something in the meantime. Dennis and Mike -- Dennis, I thought I heard Mike say something about a finished -- about an interim step might be a performance standard for some of these SOP's -- the interim proposals. Do you like that? Before your clients kick you, answer.

MR. JOHNSON: I have to see what it is. It depends. I'm a lawyer. It depends.

MR. BILLY: I think I'd like to pick up on that. You will find that in the specific discussions planned on the near term measures that there is in the thinking that will be reflected from the agency several examples of performance measure type approaches so I'd like to try to move to close this now. It will come up in that discussion in fairly specific terms. There are two people that wanted to be recognized -- Joe -- and then I'm going to wrap it up.

MR. POCIUS: Okay. Thank you, Mr. Chairman. Wait till he switches the electricity over here. Thanks.

Dennis --

MR. BILLY: Identify your --

MR. POCIUS: I'm Joe Pocius with the National Turkey Federation. Dennis broached one subject so I won't belay that. I do want to comment though. There seems to be an unfortunate repetition of an unfortunate sound byte that has made it into the press and that is that HACCP will do away with inspectors in the plant. Dane mentioned earlier that that's just not the case and that's not the intent. We cannot operate without inspectors to do the monitoring as
per HACCP. We need someone in there to do that. That does not
obviate the presence of inspectors in our plant and I would hope that
if an inspectors sees a load of meat which they suspect to be
contaminated they would tag that. That's part of their job. That
should not change under HACCP. This sanitation issues that Rebecca
mentioned should not change and there is a monitoring section within
an SOP program as well. I guess there is a disconnect here as to what
role the inspectors will play. Certainly it will change. Certainly
there will be a more efficient way of operating. But just as certain
their presence will be there. We need to get to that and get off of the
"A" here, Mr. Billy. We spent an awful lot of time. I've been biting my
tongue cause as we go on we have no choice but to start to discuss
the details of this under a section which we're supposed to just speak
of generally. So I'm sure we'll all jump in and discuss it further
later. Thank you.

MR. BILLY: Great. Art, you have the last word.

MR. SYRING: My name is Art Syring. I come from Springfield,
Missouri. I'm a federal meat inspector. I had the privilege of working
for ten and a half years as a relief inspector across the State of
Missouri. I also had the privilege of being in an Oscar Meyer plant for
the hot dog portion in Missouri. They have a full TQC. I worked in
plants where poultry plants have NELS. Turkey plants have NITS and
it all comes down to one thing. I don't care how good you are, it's only
how good you back your system. I find a lot of fabrications of records
and in the NELS programs they'll go out there and they'll do these
tests and this is all plant-generated procedures and policies. It's not
government. The plants set their own programs and then they can't
afford to follow them because they're too strenuous and they cause a restriction on their operations and they have to slow down. Time is money in industry. It's not in inspection. I'm a consumer advocate. I work for the consumer and I'm proud of it. When those consumers come and says what are you giving me to eat I want to say I gave -- the plant gave them the best money can buy, not government. We're only there as eyes for the consumer to monitor your processes, not our's. When you establish this HACCP program that we're all sitting here talking about I want to be proud too because I want it to enhance what I do, not take away. I want to be there with you, I'm for you, let's go with it, but let's enforce it and let's not just make a paper chase again like we did on everything else. That's all I got to say.

MR. BILLY: Okay.

MR. POCIUS: I'd like to say, Art, -- -- Foods and I'm sure that Oscar Meyer wasn't falsifying any records.

MR. BILLY: With that I'm going to call an end to this morning's session. Several people have suggested that it's not necessary with the cafeteria right here to have an hour and a half for lunch. So I'd like to request that everyone be back in an hour. That would be at a quarter to two. Yeah, quarter to two.

(Luncheon recess was taken)
MR. BILLY: I'd like to get started again. Everyone be seated. Art Syring, one of our inspectors, wanted to at the outset clear up something that he mentioned during the morning session. So, Art.

MR. SYRING: Yeah. I'd like to clear something up. I didn't come here to point fingers at any industry or any organization. I come here to point the facts. I guess when I mentioned the Oscar Meyer I was relating to them as the largest TQC plant. I've been into the smallest. I'm making a statement and I want to make it very clear. Industry sets the standards. You ask us to follow them. You better make sure you follow them cause I guarantee you one thing, when the government tells me that's my job it is my job, so Oscar Meyer, I'm not saying they violated their programs. They're the ones that know or the inspectors in their plant. I'm not here to point fingers. I want to get that cleared out. Thank you.

MR. BILLY: If you look at the agenda for today we had quite a discussion about near term measures and I understand there are probably many more points that could be made. In that regard, we walked right up to -- the sense I had was we're warming to get on with the specifics in that regard. We also talked about HACCP and there were some very broad statements of support. We've talked some about merging HACCP in the current system. There will be more coming up on that this afternoon. We did not talk at all about timing, agency implementation, and industry adoption. There were some statements about that and the need for transformation and so forth. My suggestion -- what I'd like to do is to hold off on timing and the more I've thought about it, it might be a good topic for the last day
after we've talked about a number of the other things. I don't want to ignore it and I think it's important. There are a lot of very good comments and suggestions about timing in all the comments we've received but I'm going to move that to the last day and get on with the next area which is FSIS oversight of HACCP and the changing role of inspectors under HACCP. In that regard, hopefully all of you have received when you signed in a paper -- a discussion paper titled Overview of HACCP Proposal, FSIS Oversight of HACCP and the Changing Role of Inspectors Under HACCP. This paper is designed to do several things. It does not do other things and I just wanted to talk a little bit about that before we get into the specifics. If you look at that paper, under Roman I there's perhaps in little different words there's a characterization of what the original proposal -- what the objective was -- with regard to this area, what the objection was. Roman II -- Description of Comments -- is sort of in capsulation of the comments but there's a very important point. This summary of the comments is not designed to summarize all the comments we've received with regard to these subject areas. Rather it's in capsulation or summary of the comments that are associated with the key issues that come out of all of the comments or that were suggested during the scoping session that we had. We will, in fact, in the final rule address all of the comments received. We've read them all already, we've got summaries of them, and no comments will be ignored. What we've tried to and what was agreed to, a few pages, is to highlight and give a sense of the comments as they relate to some of the key issue areas to facilitate the discussion so I wanted to make that clear.
The next section deals with current thinking on selected issues and this is where the agency now in trying to move the ball forward if you will is identifying what it's observing as points or concerns that must be addressed and some options or approaches to addressing them and that's what this paper is designed to do and hopefully will facilitate the discussion and the understanding in terms of these areas in terms of inspection under HACCP and the role of inspectors. To further that, Bill Smith is with us and Bill is going to highlight some of the key points that are in this paper as a precursor then to having a very specific discussion and answer questions about the role of inspectors and inspection under HACCP.

MR. SMITH: Well, from our discussion this morning we wanted to share with you some of our thinking, at least developmental philosophy of what an inspection role would be like under the near term initiatives and the HACCP plan.

We see three basic components through an inspector's role and that would be validation, verification, and enforcement and I'd like to just briefly, if you will, describe those.

Under validation, what we're looking for is to determine the credibility of the plan, whether it be an SOP or the HACCP plan that it will be used as the operating mode in that plant. As, for instance, in a sanitation SOP, the regulation proposes specific areas that should be covered in a sanitation SOP such as the cleaning of equipment, a preoperational sanitation inspection to check the effectiveness of that cleaning, who will be responsible for perform those activities and where they would be identified. And then in an operational mode that, again, there is a responsible official to identify and react to a
direct production contamination situation, whether it's environmentally from equipment or facilities or from personnel, either in personnel hygiene or a plant employee's production handling of the process that's going on. We would then be looking for the inspector then on the first day that the SOP is to go into effect to take a look at the plan that the plant has and compare that against that criteria and if those major areas are addressed in the SOP that's what we would see as a validation effort. And the same thing for the time temperature. The anti-microbials, while they don't require written plan, there is in the proposal those specific uses and, again, the inspector would be determining that the use that has been chosen in that plant meets the regulatory requirements. In the HACCP plan, again, we've gone on. In the proposal it talks about that the plan should be developed along the same principles and so the veterinarian or inspector in that plant again would be looking to see that a hazard analysis was done, that a critical control point has been established to control that hazard, that a critical limit has been identified for that critical control point, the monitoring activity has been described, record keeping has been described, that if there's a failure at that critical control point that there's a method for dealing with corrective and preventive action, and then, finally, a plant verification activity to insure that the monitoring activity in the critical control points and critical limits have been met. We see that as validation and therefore if those seven principles have been addressed in the HACCP plan then that would be the basis of our validation and that establishes the credibility of the plan. Once then you've established that the plan is valid, whether it be an SOP or the
HACCP plan then you -- we would see ourselves moving into a verification mode.

Verification mode we see being conducted under two basic procedures. One would be record review of the CCP monitoring activity and the plant verification activity. And then we would see, for lack of a better word right now, hands on activity, where through direct observation, either visual or performing a task or observing the plant performing a plant verification task, that the inspector would actually take a sampling of CCP's and see that they are in control or that there would be a sampling of the plant verification activities again to determine the process that's been identified and the validated plan as being followed. That removes us then from a detection mode to a process, monitoring, and analysis mode and that's how we see ourselves in the regulatory arena and that was recommended, I believe, by the National Advisory Committee, micro-criteria for food. That would be an appropriate role for a regulatory agency. And the enforcement arena then we are looking at, again, with SOP's or the near term initiatives that they would be in place on that first day that the regulation -- ninety days after the final rule as it proposed now. And that failure to have those in place would result in some kind of suspension action until that basic criteria was met and the same thing with the HACCP plan that if the first process 01 that's identified in the regulation is -- should be in place twelve months after the final rule and, again, if a HACCP plan is not in place then we would see ourselves taking that same role -- that we'd suspend that particular process until that particular criteria was met.
Under the verification inspection, inspectors, again, would be monitoring to see that the plant is following their SOP or their HACCP plan and so, again, we would not be in the mode as earlier described this morning. Like in Kansas City, we would have expected the plant to conduct the pre-operational sanitation in that situation and have identified direct product contamination situations and if they had controlled those we have no deficiency at that point because the SOP specifically states if there's something wrong and the plant takes the action to correct it we do not have a system failure at that point. We have a system that's operating and that's a major change -- that we're not going to jump in right away and take the action that we're going to expect the plant to follow their SOP and take that action. The same thing with the critical control point and monitoring in a HACCP plan, for instance. If we have a poultry product being produced and the cooking temperature is a hundred and sixty and the product is pulled out at a hundred and fifty eight but the plant employee recognizes this and tags that product and holds it, puts it in the cooler for further analysis of what's going to happen, then the plant through a process and authority or some means determines that the time temperature was adequate or that it has to be recooked at a certain time temperature in order to make that product meet the critical limit and the plant does that, again, we have no deficiency because the plan is working. What we will be looking at is to take action when we determined the plant fails, and, again, let me just give a quick scenario, both in the SOP arena and the HACCP arena as an example.

Let's say that we have a small operation that -- HRI operation -
- and that they're vacuum packaging for raw pork loins and it's the end of the day and an order comes in for five fully cooked hams and the production foreman is responsible for the SOP in that plant and that he instructs the employee to into the fully cooked cooler and bring out five fully cooked hams and vacuum package them. Well, he then observes the employee going in and doing that without changing their clothes, without washing or sanitizing their hands, bringing those cooked products into a raw product area without washing or sanitizing the equipment and then proceeds to vacuum pack that product and that is the responsible official for the SOP and the inspector observes that then we would be in the mode there to determine that we had a failure of the SOP resulting in retention of those five fully cooked hams and rejection of that equipment and then the corrective action that we would be expecting in that situation is not just to wash down the equipment but to correct the failure of this SOP. This gets to what Rosemary was saying this morning. Do we fix the individual incident which has been our past history or do we take a systems approach to deal with the incident but also to put something in place to prevent it from reoccurring. The same thing in a HACCP situation. In that situation I was talking about where we cook the poultry to a hundred and sixty and let's say it was on a timed cycle in a smokehouse and the time cycle was met and the production employee again pulls that product out, does not observe or document even though that was the monitoring activity described in then plan, that the product did not meet temperature and go ahead and pushes it into the cooler and then it goes through its normal process and let us say the production or the shipping foreman has been identified as the
person who would do the plant verification activity which would be
review all monitoring records on the CCP's and then any sampling that
was done prior to shipment and the product's on the truck ready to go.
Again, an inspector after doing a process review determines that it
did get through all those steps and no action was taken then we have
-- we would see a HACCP plan failure and, again, the regulation as
proposed now would suggest that we would suspend that operation for
fully cooked keep refrigerator products and that the only correction
for that would be, one, to deal with the specific product, but, two, the
HACCP plan would have to be adjusted to address that process failure
and have to be revalidated then again to get back in operation. So we
see ourselves looking at taking a systems approach, a sampling, a
record, or hands on activity or combination thereof to determine
whether the system as described by the company is working or not
and if it is, including taking corrective actions when a problem goes
wrong because we know that plants are not going to work at a hundred
percent compliance all the time. Things happen. But if the plant is
initiating action to address those situations then we have no
deficiency again or no process failure. What we have is system
compliance. On the other hand, if they're not, then we feel that would
be our role to act in that situation. And so basically that is the
foundation for -- for how we would be acting in that -- in a SOP or
HACCP plan environment. Again, basically validation to see that the
plan is being used, whether it be the SOP or the HACCP plan is
credible, meaning that it meets either the requirements of the
regulation or has met the seven principles and then to verifying the
once you know you have a credible plan verifying that that plan's
being followed and taking action when you either have direct product contamination or a systems failure. And we understand that is a move from where we have been in the past. We understand that we have a lot of work to do as supervision in that system. We understand that there's a training process that has to go and we are looking at changing the way we train to insure we can equip our employees with a just in time concept that when near term initiatives come on that they be ready to deal with those specifics, that when they need to have validation expertise that, again, they will be equipped and able to do that and when they go into the verification mode, again, that they be equipped to do that. So basically in a broad sense that is what we are thinking about right now for validation and verification and enforcement of both near term initiatives and HACCP plans.

MR. BILLY: Okay. Let's start over here. Mike?

MR. DONOVAN: Hello. I'm Mike Donovan from the Association of Supervisory Technical Professionals and one of my questions to you, Bill, on that particular scenario that you just laid out on the case of the chickens being cooked, pulled out of the smokehouse, for instance, and put in the cooler at a hundred and fifty eight degrees, when would the inspector take his action? Does he have to wait until it goes on to the truck or how is that going to be set up? Because I can see where there could be a situation -- I'll just play devil's advocate -- that the individual rolls it into the cooler and the inspector notices that and he doesn't take any action and he goes to tie up the product and the company says well, I just didn't get around to put it in my records yet and I can see where that could end up being a situation where the company is saying that the inspector was over zealous and
the inspector said, well, they had no intentions of doing this and controlling the product. How are we going to handle situations like that one?

MR. SMITH: Well, again, I think what we're looking at is a sampling of -- of CCP's or plant verification activities. So in the -- especially in start up and if we had one CCP failure that we would need to be reacting to that. But I would think we would need -- in order to determine a HACCP plan is effective or not you need to look at more than one CCP. And so if you had a CCP failure at the receiving dock and then a CCP failure at the cooking area and then plant -- I think we would have to make the determination whether we're dealing with a single incident, which is still important -- we'd still have to act -- or whether we're dealing with a system failure and I think we need more than one point in order to make that determination. So those are things that we have not fully worked out yet and hoping we can get some guidance from this group in dealing with those situations that you just mentioned but we want to move to a system, I believe, where we would look at a number of points to tell us that the system's failed as opposed to one point failing and then we would deal with those differently.

MR. BILLY: Okay. Joe and Dell.

MR. DUFF: I'm Joe Duff, an inspector from Indianapolis, Indiana. And I just have a couple of points of contention I wanted to make and the first is to find a ground that we can all agree on and that's that the worst plant manager in the world is your inspector. But you keep giving us a job. And quite frankly I don't want the job. I didn't apply for it and I really think you need to take control of that situation and
run your plant and stop giving it to us. We have a very specific
function that we perform there. It's well defined. It's not a secret.
And if we're operating outside of those guidelines we have other ways
of dealing with -- internal ways of dealing with us and so we're
pretty much under control quite to the contrary of thinking some. I
also wanted to point out that the issue's made of inspector using
common sense, I just wanted to make the point that at one point this
year when an inspector used common sense to make a judgment call
and give the plant a chance to correct that problem he was accused of
bastardizing the system because he didn't make an issue out of it,
just gave them a chance to correct the problem. I'm saying, where are
you standing on these issues? You want us to write it up? You want
us to give you a chance to correct it? The call is your's but you're not
taking it. I think the ball is in your court and you just don't want to
dribble it.

MR. BILLY: Dell?

MR. ALLEN: I'd like to get the electricity on down there. I think
we need to broaden inspection's role in that HACCP format, Bill. And I
have the opportunity of being with a company who has representation
plant-wise on both sides of the border, being Canada and U.S. And I
know you all are well aware of what's going on in Canada. In our
Canadian facility -- and first of all we have fully operational HACCP
plans in all of our facilities -- we started in 1991 developing. We
developed, we wrote, we implemented, we redeveloped. And that's
the thing I think we need to all keep in mind. The whole part of
HACCP is a very dynamic thing. It changes -- in some cases,
to be kept very definitely in mind. But on the Canadian side, the IIC in
Canada there in our plant, she sits as a sitting member on our food
safety committee. She deals with us as we deal with the HACCP plan
in that plant. She's a contributing member to it -- a very valuable
contributing member to it. All of the ag Canada inspectors -- we
have a training session for every employee that walks through the
door on HACCP, on food safety -- very basic in nature to the hourly
employee. Those with additional responsibilities get additional
training. They go through that training with our people. It's a very
coooporative situation because we are in it together folks -- the
inspection force and ourself. I mean whether it's one of those things
that we can have a fruitful relationship as long as we will contribute
to it and make it that way. And I'd like to see this side of the border
at least consider that approach. We have invited that type of
participation in the States and very honestly have not gotten
favorable response to it on the agency's part.

The other thing I'd like to say is that everything we do needs to
be made as objective as possible because invariably when it's
subjective we get into very deliberate arguments. We have individual
private companies right now that HACCP is happening around us,
whether we want it or not, it's happening. We have for the last two
years had enumerable audits from various people that we supply
product to that come in and audit our HACCP plan and they give us a
score. It's a numerical score -- numerical rating. We have an in-
house system that does the same thing. If we have a plant that
scores a ninety or above in our internal audit that plant gets to get by
with less audits then the one that scores below that. It's a very
workable system. It's a very objective system. But in order for people to go in and intelligently perform that audit they have to know and understand what they're looking for in the HACCP system and we would hope that the agency would take advantage of those experiences of people like the fast food people in this country who are already doing this thing who have people who are actually trained in that area -- you know -- as you adopt your own plan. I think it would move us all down the road a lot faster.

Finally, one more objective thing. On pre-op sanitation it's a bug of mine. We have an internal system that's very objective and yet subjective. It's combined because microbiology is a -- I'm a pseudo microbiologist. And I'm beginning to wonder if there is true microbiologist by the way. But we have a system where we track the pre-op sanitation program with microbiology. Every piece of contact equipment they have in the plant on the kill floor is identified in the computer. We random sample it. We test five percent of those daily and we track the microbiology on that system but it's three days after the fact -- always is -- because of microorganisms being -- and microbiology being what it is. In addition to that then, we have a visual system that goes with it and we score a certain percentage at random and the two are combined into an objective score and lets us evaluate objectively our clean up crews that clean up. I've offered that, again, that program to the agency on a couple of occasions and invited you to come out and see it in operation. Yet to see anybody come to do that. But that invitation is still open. And I would love to -- to me this is the mode that we've got to get inspection into. And that inspector -- I fully agree with everything that the other people
have said. We need third party presence not because they're bad guys
but because when you work in a facility day after day after day you
tend to get barn blind. And you need that additional set of eyes. You
need those people coming in and pointing out where you have been and
gotten barn blind. And, again, to me, that's how the agency needs to
really function and help us cause you can be a great help to us. And I
would really implore that you go north of the border and talk to the ag
Canada people in seriousness of how they have approached this whole
issue. They will have their system fully going by October of next year
and it's been a very cooperative effort between industry and ag
Canada. It's really a treat to work with them. Thank you.

MR. TAYLOR: Dell, if I just make ask a question to follow up.
There's some very legitimate but competing interests or
considerations in what you're saying. I mean one is obviously we need
to work together and learn from each other and there's a lot that can
be done collaboratively to address -- to make progress on food safety.
On the other hand, one of the things that we're seeing a need to do and
part of the thrust of our program, frankly, is to more clearly
delineate responsibilities between the plant and the inspector and
clarify some of the lines that have become blurred and which through
the combination of command and control approaches to regulation and
our inspectors perhaps taking -- you know -- by default or otherwise
taking more responsibility for management of plant operations than
they ought to in the end the concern is that under the current system
as a function of the system not clearly delineating responsibilities
and maintaining the distinction between the plant responsibility and
inspector responsibility, neither the plant nor the inspector is doing
the best job that a plant can do in producing safe food and that an
inspector can do in providing oversight. And so we're frankly looking
to maintain that distinction. And my question, I guess, is how do --
do you think that's a good idea and if it is, how do you maintain that
distinction in the Canadian model where you posit -- you know -- the
IIC sitting on the company's food safety committee? I mean how does
that work as a practical matter in maintaining some distinction
between roles?

MR. ALLEN: Well, first of all, she does not back off of her duties.
I mean that's the first priority. Nor do we ask her to. But because --
just like in any -- when you have two groups of people working in the
same facility by her being present there she can receive input from
the people that work for her as to the way that we can improve the
system. And it may be very definitely counter productive and to us
from a productivity standpoint. But she brings it to the table and if it
is a legitimate serious thing we will work with her. And I think she
still has that right because she is the regulatory arm there. If it's
something that needs to be regulated and enforced she steps down on
it. I mean it's a true partnership in that situation. Again, the whole
issue, I think, and all of the things that we do we need to get it to
where it is an objective science. It will never be totally objective.
But we need to take the steps that we can to get it to some type of a
measurable objective thing to the greatest extent that we can. And
those tools are there. We are bright enough folks if we can -- you
know -- cooperatively sit and think we are bright enough to figure
this think out. I cannot believe otherwise. And I know if you look at
our pre-op sanitation program, for example, I'll bet you could improve
it for us. I'd bet that with your experience.

MR. SMITH: I would just like to state I agree. The sanitation operating procedures would encompass if those were the procedures you use in your plant to insure that sanitation is met and there's no direct product contamination going on in that situation that's what we would be validating and verifying and using to determine the system is effective which is a little different than what we're doing today.

MR. BILLY: David.

MR. MORRIS: I'm David Morris and I'm here representing the National Meat Canners Association and I'm also a member of the industry.

I feel like I'm a little bit wedged in here out of place because I didn't realize we moved off the near term objectives and we skipped "B" part of that. But maybe what I'm going to say will also help with some of the things we're talking about. If we look a little introspectively at what's happened in the canning -- in the meat canning industry I would say the USDA and the industry has not taken credit for having a HACCP program in effect for nearly ten years. You talked about these things came out in 1985. 1987 the canning regs were put into effect and essentially if you look at every aspect of that canning regs we have a HACCP program that we've had to live by for those years and I shouldn't say live by. We have joined in on this and as the National Meat Canners Association years before that we were working with the Department to develop things like how do you evaluate abnormal containers, what do you do about process deviations? These were things that we worked on as an association
with industry members and your Department to develop what is an
abnormal container. When you see it what do you do with it, how do
you react, what are the standards, what do you do, is one-tenth of a
percent too many, is half a percent too many, and what is the
proposed standard that we should have? And we developed together
all of those things and they culminated in this regulation that we
have. Also, in conjunction with that, almost every major canning
plant in the United States has a total quality control program that
says in essence we accept the responsibility to control the program
that you approve for us. And there is a working relationship of
inspectors in those plants. We've worked that out. I happen to have
been the plant manager of the first total quality control program that
went into effect in the United States. It was about 1984 with the
Dial Corporation in Ft. Madison, Iowa -- canning plant. We sat with
the inspectors and it was a very difficult time for all of us. I was a
young buck saying, hey, you know, I'm in control of this place and the
inspector in charge says it's my responsibility. Until we finally sat
down and talked and worked in conjunction with like what he's talking
about in Canada, the thing wasn't working properly. But we have
those things in place. You ought to take credit for it. My God, you've
had it for almost ten years. What we're saying is, the National Meat
Canners Association is you ought to look at that and say, hey, there's
no need really to change what we're doing with canning. You have it in
place. Don't lay some more things on -- when I talk about layering I'm
saying I've already got the HACCP program, why give me any more.
Our safety record is very good. Consumers know how to look at a can
and tell you whether it's a problem. Unlike a piece of fresh meat,
those microbes hide in there. In my can, they swell up and blow up
and they leak and they do all kinds of things. So I think you should
look beyond us. You should accept that you have a HACCP program and
we're running it and maybe you ought to step back and look and see
how the inspector, the plant, and the control systems are working
already in conjunction with the canning industry and the total quality
control programs in there and I think you'll get good clues about how
this system can work and we're more than happy to work
cooperatively with you to show you anything we're doing.

MR. BILLY: Merle?

MR. PIERSON: My name is Merle Pierson. I'm here on behalf of --
--. I'd like to address the overall -- -- (microphone not working).
-- -- all very critical issues. The role of regulatory is in
verification and we agree with most of the points that were
presented here by Mr. Smith. There were some nuances in terms of
definitions that I think need to be worked out -- verification,
validation, auditing. Hopefully, the National Advisory Committee can
clarify some of those terms further. A very key issue is how do you
develop and implement this system. It's just not a wholesale
immediate change. I think that would be a very serious mistake.
Number one, industry has to have in place effective GMP's. They must
be in place. So we support the concept of standard operating
procedures for sanitation, etc. I agree with the earlier comment that
in fact what's probably needed is a separate trading program relative
to GMP sanitation. I would agree that that, in fact, should be done in
conjunction or cooperation with the agency. Quite frankly, industry
and regulatory need that common understanding. And this is where it
takes us to HACCP. I had the opportunity for the egg products people in USDA before they came into FSIS to do four HACCP workshops for egg products and those workshops included both inspectors and industry. And it was an interesting change in mindset in both groups. The beauty of HACCP is it offers a commonality of understanding. We should know where each other's coming from. And we don't need to separate that. I think it's a great value when you have that training in conjunction with each other because then each group understands better their roles and where each other's coming from. Very important concept too. We just can't develop HACCP plans. We need to go beyond just how do you write a HACCP plan. The question is, how is that plan implemented? And it's not a wholesale implementation. It's an incremental implementation and generally it's one critical control point at a time.

The other thing is, how do you maintain that HACCP system? And there needs to be training in that area. Another question is, how do you verify that system? And there should be commonality of understanding relative to verification because, quite frankly, verification is -- can be very complex. In the validation part, for example, of CCP's can be very scientifically complex also. So we fully support the concept of HACCP, the adoption of HACCP. It should be done in a very careful systematic manner and -- you know -- there should be actually further education programs or training programs relative to all phases of HACCP, not just how to write a HACCP plan.

Thank you.

MR. BILLY: Irwin?

MR. MUSKAT: Irwin Muskat, Jack Pack Foods. Bill, I'd like to
address this to you but before I get to that part. I want to address something that Dell Allen said. In our HACCP programs and tied in with our ISO programs we publish charts that show our PDR’s, our performance deficiencies by department, by category, by inspection personnel. We publish that. We post that for all of our employees to see. We offered through local inspection and all the way up to my personally speaking to Tom Billy that if it was available to us we would have our inspection personnel in our own training programs for HACCP and ISO. I gathered that through political and public probable problems that did not come to prevail. But our QA Department has told me they do not report to any executive other than the QA executive when they have to do something with product that is other than its original intent. But all of that comes down to the fact that we’re a TQC plant and I think our initial date was 1981. The biggest problem that we ran into with TQC and that I see from what I understand from what you’ve discussed, Bill, is that we are going to be just one step off of traditional inspection. In order for a HACCP program or any program like that to work you have to be able to verify that the program in its entirety works, not just at one critical control point. When the inspector has the option to step into the middle of the program and make a value judgment that the program isn't working the inspector has basically defeated the entire concept of the program in that the double checks and triple checks, whether it be the person that's in charge of the program or the validation of paperwork has never had an opportunity take effect. And, yes, so this time he stops at a critical control point number 3 and next time he may stop at a critical control point number 1 but every time he stops
at a critical control point you've never found whether in fact the program is working properly. If you're not going to allow the product and the process to go to its full extent and then decide what you're going to do with it then you haven't -- you really don't have a HACCP program. That doesn't mean that the inspector shouldn't document that he found a deficiency at a critical control point. Of course he should document that. And I would think that any good program would have some kind of a rating schedule that if the inspection personnel came in and did an audit function and found that at certain critical control points we have weaknesses then we have a weakness in our program that has to be addressed but you can't make a determination that the program itself fails verification because of that and I see the traditional inspection -- as I said -- just one step away.

As far as validation is concerned, what kind of validation is an inspector going to have ability to process? Is it going to be an arbitrary validation or are you going to process defined criteria by which this program can be validated or invalidated?

MR. SMITH: Let me address those. First, on the verification, that's what I was hoping I was describing that we are not going to and in the instance Mr. Donovan talked about that we are going to look at several points along the continuum, whether it be critical control points or plant verification activity, to make a determination of whether we have a systems failure or not. So I'm in full agreement with what you said and that's -- what we are conceptually looking at is the design for the activities we'd be doing. The one CCP failure in and by itself is not a HACCP system failure. And that's why I was indicating we have to look a sampling of CCP's and then based on
those results we would make a determination whether the process is in control or not in control.

On the validation, again, we go back and what we'd be looking for in a start up situation would be that the seven principles have been addressed, that a hazard analysis has taken place. We're not going to be making a determination on whether -- whose method of hazard analysis -- whether it's an appropriate or a valid hazard analysis. We want to see that a hazard analysis has taken place. We want to see the critical control points then for the hazards that have been identified that they are controlled at some point in a critical control point. Again, it's not up to us to say whether that critical control point should be there or not be there. If the plant has established it to control that hazard then we will be following that. That a critical limit has been established and let's say somebody roasts pork has established a critical limit of 148 degrees at a seventeen minute hold and at ninety percent humidity that results in a 5-D reduction and you call 015787 and 70 and salmonella. We're not going to be asking our veterinarians or inspectors to determine whether that's adequate or not. What we are going to be asking them to see that there's some support in the form of scientific data that the plant -- that has to be assembled in the HACCP plan -- something there to support that. And those are the kinds of things that the basic seven principles have been addressed. If our inspection personnel question whether a CCP is appropriate or a critical limit is appropriate we're going to provide them a mechanism to get that to the science and technology people within the agency who have the expertise to make that determination and then after that
determination then we would -- I would see some action being taken if we're not in agreement. But we're not going to have the in-plant people making those kinds of determinations other than, like I said on that critical limit, we would expect some -- whether it's evidence of a heat penetration study -- some kind of evidence to support that critical limit unless we're using regulatory requirements that exist now. So that essentially is what we'd be seeing at least at start up. You know -- down the road we would be equipping our people to be able to make those calls but at this point that's what we would see as initial validation activities.

MR. MUSKAT: Going back to verification for one minute. There's a difference between the inspector observing a deficiency at a critical control point and stopping the operation there so that the operation doesn't have a chance to validate that it's effective or documenting it and keeping record keeping by record keeping go through verification and audit procedures to see how effective the procedure is. Once he stops it, which is what he does now, you no longer have an effective program. If he's going to be allowed to let it continue to its end item examination or its end point so that there's documentation review by the plant then we have a system and then we might have a system failure and that should be documented as such. If that clarification is there that's fine.

MR. SMITH: Absolutely. That is what we would be putting or that is our thinking now to get into training because of the system's approach because -- because if you look at the proposed enforcement action which is suspension of that process you have to have documented evidence that we have a system failure and so we need to
inspect such that we'd have the evidence to support an action of that
type. So we would be teaching or training our people to take a
system's approach, both in record auditing and direct hands on and we
are working with -- as suggested we'll work with all auditing
agencies but we have been working with a number of other federal
agencies that have expertise in auditing the records to build a case or
to make a determination from a number of observations and we're
looking at a lot of the industry to help us and what are those tolls
that we use in record auditing and direct observation and statistical
analysis to be able to make a call when a number -- if a number of
CCP's fail then can say the process is in question. And I agree that
the plant needs to be allowed to have their plant verification activity
take place and so if that calls for a review by the QA at the end of the
day on each lot that the CCP's have been met then that has to be
factored in to determining whether you have a system failure or not.
And I agree. We would need to be documenting the specific incidences
but that is not a systems failure.

MR. MUSKAT: One last point. Still on your subject matter. If
inspection assignments are going to basically remain similar to the
way they are now and there's going to be an inspector in every plant
you're not going to be taking advantage of HACCP and what HACCP is
designed to do and I heard -- maybe I inferred it from the
conversation -- but if a smaller plant -- maybe a huge plant is going
to need an in-house inspector to be able to do the audit functions I
would never even do it that way if it were my choice. It would only
be audit teams going around and all the inspectors would be on audit
teams and they would be either announced or unannounced audits
going through these plants to verify inspection. And if you want to do
-- this is the way we're audited now by ISO. This is the way we're
audited by AIB. This is the way we're audited by all of our suppliers
and our customers. Excuse me. Not our suppliers. MR. SMITH: We'll
take that as a way -- I think what we need to have the activity drive
-- what we do in those plants -- and that's a good suggestion.

MR. BILLY: Art?

MR. SYRING: I'd like to answer some of that rebuttal to his
statement, you don't need inspectors.

MR. MUSKAT: I didn't say that.

MR. SYRING: You said you'd like -- if you're going to be
monitored under HACCP and under the HACCP program that's the
reason why it's there then you would have less than a full time
inspector in the plant.

MR. MUSKAT: Less than full time. I didn't say --

MR. SYRING: Less than a full time. You don't understand right
now that in ninety percent of our plants on patrol assignments -- I
patrol three plants and those three plants under the old system -- I
work with a five hundred percent workload. I'm not in that plant full
time anyhow. When I come into that plant I find several deficiencies.
Somebody's out of bed. It ain't me. These programs that you're
writing you have to understand you set the standard. I'll say it again.
Just like under sanitation. The plant -- the one plant that I go into
has run a perfect low deficiency swab test on sanitation. They swab
every morning. You go out there and you see them swabbing the whole
place. The plate count is zero. You look inside the equipment or the
people's equipment they're dirty. They're not clean. They're
unsanitary cause they have meat scraps, particles, residue from prior day's production. They'll form all this stuff down, they'll take their sanitizers, pull the top, and we go look at your record and it's perfect. The only way we're going to know to protect the consumer to know what we're doing is actual verification and that requires us to come to your plants. Right now, under PBIS, we're assigned how many times we visit your facilities -- twice a week. You're supposed to have responsibility for five. My computer tells me I'm going to be there on a random basis. It doesn't tell me when I'm going. It's selected weeks in advance. And you're telling me you don't need inspectors. If you got problems you do need inspection. You need a good enhancement with HACCP over inspection to work together in unison to make a good program work for the consumer. That's the main deal here. We're all sitting here wanting to better ourselves. You wanting to better yourselves to make more money, produce a wholesome, clean, and sanitary product for the consumer. I want to make sure the agency gets their money's worth when I'm out to working.

MR. MUSKAT: I totally agree with you. I didn't infer nor do I recommend that we do not have inspection. What I'm recommending is that we have audit function inspection where you're verifying that we are doing what we say we're doing and I think that's what you just said. We're not going to be able to get away with anything like that. You are going to have audit teams hopefully that are going to come into the plant as inspection personnel -- you and several of your colleagues would be coming in as a team or however you want to determine you want to do it and you're going to go through our plant
with a fine tooth comb and verify that we are doing what we say we're doing.

MR. SYRING: That's FDA. This is USDA. As far as -- we are a consumer protection agency. That's what I consider USDA is. We only rely. You set a program. I'm monitoring -- I know of plants -- I know in Kansas City one inspector covers twelve plants and that's just a token visit. They're doing that already. But some of them plants are under restrictive measures because they have fallen out of bed. Managing QA people have to do one thing -- control their own processes. You don't pay my salary but I can guarantee you one thing. Somebody pays your's and it's not USDA and it's not the consumer. So if comes to a point of making a decision whether you will or will not run that plant that person on top of you says I sign your check, you'll run it, and you will. I won't.

MR. BILLY: Lee? Caroline?

MS. DEWAAL: I have a series of questions for Bill Smith. It's Caroline Smith Dewaal with the Center for Science and the Public Interest.

I think the way I'm going to do this, Bill, is just do them all at once and then you can respond.

There are a couple of things you said that really are great concern to me. One is that you're going to go through a checklist to make sure that the companies comply with the seven principles of HACCP. And then you said later that the in-plant inspectors wouldn't be reviewing the adequacy of that hazard analysis or the PCP identification or the critical limit or anything else. Somehow that is going to be handled in Washington. How is that going to be handled?
My second question is you said that once you've gone through this checklist that this would be validation of the plan by FSIS. In my book, that's simply doing hazard analysis without any assessment of whether they've done it correctly or whether they've identified all the hazards with their product is not validation of the plan and I would recommend that the agency consider instead the validation being by FSIS of those plans include both a review of all of the elements of HACCP together with the adequacy of that review -- whether the plant has actually identified all their CCP's and whether they've identified appropriate critical limits and appropriate monitoring activities, etc. together with microbial testing to validate that the hazards identified are actually being controlled for. And I am reminded of USDA's pilot program where they found in the after implementation of HACCP in poultry plants that some pathogens actually increased in the products rather than going down. So I think that microbial testing has got to be a critical part of the FSIS validation of those plans.

My third point also is when you were mentioning the verification functions you said you would do sampling at CCP's but you did not indicate end product sampling of that product. And I want to know whether that is accurate.

And my final point is that you have said that sampling -- that before you found a failure of -- a systems failure -- and please correct me if I'm wrong -- or a program failure that you would have a failure more than one critical control point. It is my understanding that a critical control -- a failure of even one critical control point is enough to introduce contamination into a product or increase levels.
of contamination into a product. It was my understanding that a
program failure would be a failure at a CCP together with a failure to
take corrective action. So my question to you is did you mean -- did I
misunderstand it that you had to have a failure at more than one
critical control point?

MR. SMITH: Again, I was talking broadly earlier. Let me address
some of these. I did not mean to leave the impression that hazard
analysis we would accept any hazard analysis. What I mean or mean
to say is that there are several ways of accomplishing that. And
there are several published ways of accomplishing hazard analysis
and because one company does not use one published method over
another I don't see us in the role of determining which hazard
analysis method is the best out there and that's what I meant to say.
So the hazard analysis is not valid because they didn't use a, b, c's
published method so we do expect the hazard analysis that is used to
identify the chemical, physical, and microbiological hazards
associated with that product. But I do not think we want to be
prescriptive in which hazard analysis method -- and my
understanding is there are several -- that would be used to do that.
How in-depth the literature must be. We agree, again, that if
somebody wants to use micro sampling in their hazard analysis or to
identify their hazard analysis that's a valid way to do that. So that's
what I mean when inspectors would be taught the hazard analysis
must be adequate to identify those, again, three hazards that I said
but we're not endorsing any one particular method for doing that.

Again, on the CCP, as I was discussing earlier, I think you do
have to look at a number of -- well, let me first agree that a CCP by
definition that one failure that we have by definition of a critical control point that you may have a hazard introduced at that point. What I think you've said the key was and I agree that failure of corrective action. So monitoring activity has to be allowed at least to take place to identify that failure would be one, and, again, plant verification activity also includes monitoring -- independent monitoring of those CCP's and/or micro testing and those are the checks upon the checks in order to make sure that the product is safe and I believe what Mr. Muskat was saying earlier that if you stop it at that point then you -- then the system has not been allowed to work and so there is, I agree, a fine line and a public health mode when inspectors see that a product has failed a critical control point, of course we're going to act. Whether we're going to say that is a systems failure, all that has to be factored in and that's the task that I see us having to train our people which is very difficult. I see that the task of the industry also. But making that determination when we have a systems failure as opposed to one specific point. That is not to say it's not important. I would say that one of the most important things that comes out of the HACCP plan is the plant verification activities which would include sampling. Now as far as our sampling, I did not mean to indicate that verification activity would include review of records or auditing of records, hands on, and we do plan to do some sample verification. We're doing that now in our pathogen and for salmonella and E. Coli 015787 and fully cooked products and I don't see that changing. But that's in addition. We're already doing some of those so some of the things we're looking at, at least for start up, is how do we take existing programs and use those in the
verification mode so I would see our salmonella -- our roast beef 
program being used as sample verification for a roast beef HACCP 
plan.

MS. DEWAAL: Can I just interject one thing here? I agree with 
Mr. -- or Dr. Muskat -- whichever one it is -- the -- your concept of 
an audit team on top of in-plant inspectors and we have recommended 
that as the method for HACCP plan approval because the in-plant 
inspectors can't necessarily verify that the plans are -- or validate 
that the plans are accurate but if you have a team of experts going 
around doing that you would get better -- you'd get better plan -- 
HACCP plan validation.

MR. MUSKAT: I was not recommending that we have both. That's 
layering. That is not appropriate for what we --

MS. DEWAAL: I would agree with you.

MR. MUSKAT: If I could address your other question though on 
the HACCP plan. Let's say you're finding that a hazard that was 
measured at a critical control point did come to be out of compliance 
and at a critical control limits. Let's say they didn't do what they 
should have done and they didn't stop the process right then and there, 
you have another function at the end of the line. Let's say there are 
nine critical control points in that one process from start of receipt 
of product right through to the finished goods. At that last critical 
control point management must sign off that all prior nine points 
have in fact been effectively monitored and measured and they are in 
compliance. That's the second check. And then you have a quality 
assurance department someplace. There's got to be somebody in 
quality assurance in your own plant that's also verifying your records.
So there are three checks.

MR. BILLY: Ron?

MR. PRUCHA: I'd like to expand on Caroline's -- oh, I'm sorry --
Ron Prucha -- expand on Caroline's comments.

I think or I feel very strongly that the agency must go farther in
this case than it has proposed. I find very troublesome -- well, one
of the tenets of inspection has always been unilateral -- what I
would term uniformity of inspection -- that inspectors in New York
are essentially doing the same inspection procedures as the
inspectors in California and everywhere in between. But I find
somewhat troublesome, Bill's outline, in that the identification of
critical control points would be left to plant management and their
respective IIC in each plant. For uniformity of inspection I think that
may well be a disaster. Critical control points to me are just fact
and they are critical and failure in any one or more of them can well
lead to the potential of human health illnesses and problems. I would
recommend -- I've given this one a lot of thought -- but I would
certainly recommend that the agency continue on the path that they
took several years ago with the HACCP pilot plant test and all of that
but they convened workshops to come up with generic HACCP plans
for each -- for several types of products. Ground beef was one. I
think poultry slaughter was another one that was worked out and
critical control points were identified. I would go through that or go
through a procedure similar to that with the cooperation of industry,
possibly validated by the National or Micro Advisory Committee or
something like that but come up with a set of critical control points
that everybody agrees to that really are critical for every type of
process that we do, whether it's canning or ferment sausage, or
cooked sausage, but the major varieties of processing and slaughter
that occur. These ought to be given to the industry. These are the
basis. These are the minimal critical control points that you can have
if you choose to make sausage, for instance. You can have twenty or
twenty five control points -- any number you want -- but you've got
to cover those for uniformity of application and uniformity of
consumer protection.

MR. SMITH: Let me just address some of that real quick. I did
not once indicate that the inspector in the plant management would
be passing final judgment on the critical control points. What the
inspectors we hope to teach were that of the hazards identified that
there must be a controlling place somewhere to control each one of
those hazards and that failure to have a point to control those
hazards will then mean we do not have a valid plan. And there is a lot
of work going on now, I believe, to develop generic plans and make
those available. But to mandate critical control points would take
the flexibility, I think, because I don't think we could cover every
operation out there. We've already heard with the hot boning has
different circumstances and to identify minimum. We will be
teaching -- I mean we do have to teach our folks that on a cooked
operation that there must be a kill step or further a product that is
suspected to be pathogen free because it's ready to eat there must be
a kill step and then there must be a maintenance of that kill step and
we go into the thinking and the teaching and the guidelines we'll be
giving our people. But I think -- you know -- to come out and say
there must be a kill step when -- of this nature or that nature -- I
think the plants are in the best mode to determine those. It's our responsibility to have our inspectors recognize them and then if they are not adequate to be able to react to that situation.

MR. PRUCHA: I agree that there in your statement -- you know - - if you cook sausage there must be a kill step. And maybe that is enough. I think that that is the critical control point and that is -- you know -- one of them. But it makes little difference to me whether a plant makes a hundred pounds of meat -- you know -- of hot dogs a week or a million pounds, the process is much the same. It's the volume that differs and the critical control points for the production of a safe hot dog should be the same regardless of that volume and I think they can well be articulated by the agency as guidelines or expectations that anybody that makes hot dogs has to cover these bases.

MR. TAYLOR: Ron, let me just emphasize a point in terms of where our current thinking is on some of the issues you've mentioned and a response to what a couple of other people have said.

One of our roles, as Bill said, will be to validate HACCP plans and the validation of a HACCP plan is more than a checklist exercise and clearly on the issue of the hazard analysis, which is the critical first stage of developing a plan, we have to be able to know and make some assessment of whether a plant has, in fact, in an acceptable way, identified the hazards because that's what the whole plan is built on. Obviously, to do that, we are going to have to provide guidance to our employees and I think and their intention is through generic HACCP plans and perhaps other means we certainly need to be letting the industry know what we regard to be hazards in a
particular processing, particular operations that certainly need to be taken into account in designing a plan and so we are going to have to have the tools available to our inspectors and, again, working with industry to be sure that HACCP plans are addressing the hazards in any particular process that need to be addressed and we're not going to just leave that to the ad hoc decisions of inspectors or leave the industry without guidance.

We also, as we've said, our conception is that we want to have some meaningful performance standard at the end of the process whereby we can verify whether a plan designed to address particular hazards is achieving acceptable level of food safety performance. I think what Bill's trying to emphasize is that in the middle there is a general proposition we want to leave as much flexibility as possible -- as prudent -- to the plant to design the critical controls that work in their operation, to address the identified hazards and achieve an acceptable level of performance. And so we do want to try to not have a prescriptive notion of what the precise control points need to be in each plant producing a certain product. But we absolutely need to have a rigorous way to assure as we validate HACCP plans that the significant hazards in the particular operation are being addressed and I think the generic plan can go a long way to do that.

MS. MACKLOW: Tom, it seems to me we keep talking in the -- like I've said -- HACCP seems to be like jello running through your fingers. Could we ask someone in this room that has a HACCP plan to cook sausage just tell us what their critical control points are in their production? Would that be helpful to sort of make it somehow real to people to understand a little better?
MR. MUSKAT: May I read one but not on sausage?

MS. MACKLOW: Sure. Cooked sausage?

MR. MUSKAT: No. I say not on sausage.

MS. MACKLOW: Cooked product?

MR. MUSKAT: Ground beef. Do you want roast beef?

MS. MACKLOW: Is it cooked, Irwin?

MR. MUSKAT: Cooked meatballs?

MS. MACKLOW: Meatballs. Okay.

MR. MUSKAT: Critical control point one -- receive meatball batch, label packaging materials. And I'm reading off of the flow diagram and you just check and see whether that meatball batching information, labeling, packaging passes inspection. If it does you go on to forming meatballs. You're at critical control point number two when you form your meatballs you check your inspection checkpoints at that point, your measurements, your testing, your ingredients to make sure that everything there has passed. You go to cooking as critical control point number three. And then you go to your last critical control point in the process itself. Now we're only talking about in process critical control points and that's into the freezing, packaging, and labeling. In order to do that you have to have a program -- safety program that tells you what you're going to do and what your critical control point is, what you're going to do for measurement of hazards at that critical control point. I could read those. There are biological hazards, chemical hazards, and physical hazards. You're going through employee habits, GMP's, equipment condition. At critical control point one you're going through temperatures at critical control point one. You're going through meat,
age at critical control point one. Foreign objects, damaged containers, contaminated packaging material, incorrect preprinted labels for a scheduled time runs, and then you go to two and you do basically the same type of thing, including maintenance PM on equipment to make sure you haven't got foreign material that's coming from equipment that's not properly maintained.

MS. MACKLOW: So you've got four critical control points.

MR. MUSKAT: On that one process.

MS. MACKLOW: On that one process.

MR. MUSKAT: And we probably nine or ten on hamburger.

MS. MACKLOW: Yeah, okay.

MR. BILLY: Alan?

MR. OSER: I'd first like to say I disagree strongly about the -- - -. I would like to see -- it's very important in this process that the meat industry culturally change to where it is taking the lead in the area of food safety. We will not grow as an industry unless we do that. That means we can't keep on relying on FSIS to supply us with all the answers, to supply us with the regs, to supply us with all the food safety guidelines, and to supply us with generic HACCP plans. Because of the way things are set up and the way FSIS has to deal it's almost a given these things tend to be kind of minimum. It's not the best the industry can do. It's what you have to do before we shut you down is kind of the mode you have to operate in. So everybody ends up targeting at this minimum value and that's not good for us. I mean I honestly don't think this industry is going to grow until we make this shift. It's going to be a very difficult shift. And we're going to stumble, we're going to need some help, but we have to take the
initiative in food safety.

On the other hand, from the FSIS point of view, you have to make sure we're doing that. You have to still make sure we're meeting those minimums and we are in fact doing what we have to do. It's a little different role we're proposing as we get into this hazard analysis HACCP type of program. If we're not going to do that there's no point. We might as well stay where we are and -- you know -- the FSIS can supply us with the minimum requirements we have to do to get things done. That's just my reaction to that.

But what I really wanted to say was these HACCP programs are by nature non standard programs. The agency -- I understand Dr. Prucha's logic. It's FSIS logic. I think it's a little bit of a holdover. That's understandable. You've been there. It's a non standard program. FSIS has a real problem with non standard stuff. And the reason for it is that -- you know -- you have a large field force and it's very, very difficult for the field to work with non standard programs. Now, if I go back in history a little bit. When Ms. Foreman was -- you know -- sitting in your seat more or less we took the first or the last great leap forward you could call it and got into TQC -- a non standard program. However, it was realized at that point that we just can't throw our inspectors into this non standard field here. They're going to require some intensive training and that training was -- you know -- not -- you know -- I don't want to belittle what was in documents here, but it wasn't the amount of videos or in-plant site, it was go down to Texas for a week or whatever it was and really get into how do you inspect a TQC facility and in the first few years in the -- well, a little bit longer than that -- I guess the late 70's into the early 80's
we had an interesting thing taking place where plants that were
going into TQC. The inspection attitude was one of partnership. It
was one of cooperation. There was a great deal of sharing of
information and disclosure taking place and it was generally non-
confrontational but it was a nightmare from the standpoint of
inspection plans because each inspection plan had to be based on a
TQC plan which was different in every single facility. And I'm sure,
or Bill, you must have been right in the middle of that at that point --
you know -- it was a nightmare to try to keep up with these things
and every time a TQC plan was amended -- you know -- you amend
your plan of inspection. So the Department came out with an ISG,
PBIS and away went the customized plans of inspections for TQC
plants. They had a variant on traditional inspection but basically it
was the same plan except you monitored more and you verified a
little bit less. You got into two parallel inspection systems. Then in
the 80's -- you can tell I've been in the industry too long -- then in
the 80's you started to get a drift of where the roles became more
and more adversarial, where the inspectors were being told look, you
guys are not the plant sanitarians -- you know -- you're not managing
the plants, your job is go in and identify deficiencies and the plant's
got to figure out they're going to get out of it. And it seemed to take
away this idea of partnership anymore. The inspectors are supposed
to identify, define deficiencies in the plant, they're supposed to take
the responsibility -- was the big key word -- clean it up. But we got
into a very adversarial role and we're still in that role.

#4 I'm curious -- you know -- from -- you know -- Bill I know has
been there through that whole thing -- you know -- Dr. Taylor, you're
a little bit new to that. We have a much bigger problem now. We're taking an entire industry and putting it into a non-standard program. How do we put together an inspection program, how do we train inspectors to deal with completely different HACCP formats and so forth that are going to be out there? One of the easy ways to do it is to standardize everything but if you do that you're the guys running food safety then.

MR. SMITH: I think, Alan, what we're talking about the standardization comes from the seven principles. And so -- but then there's maximum flexibility within those seven principles on how you meet those but as long as we can train our folks to recognize those then we all have a common, I think, starting point. What we're talking about at least for start up also is using our receive possibly that the PBIS system could be used to generate inspection activity. And, again, that's where I was getting into earlier about CCP record auditing, plant verification record auditing, CCP inspection hands on testing, and plant verification hands on testing. Basically there's four activities that could be scheduled on a random basis and inspectors taught then that based on those tasks that you would be doing -- you'd be making a systems determination of whether that HACCP plan is -- and that's a verification activity -- is continuing to meet what it was supposed to do.

What we would see ourselves then doing is moving away from the ISG specific product task now so as the process comes up those tasks that are specific to raw ground beef in the first process comes under that right now we have approximately seven CCP's in the ISG devoted to raw sausage, hamburger, other raw products. There's
approximately -- and then all the receipt and storage and activity
that goes along with that. Because of that we'd be covering those
under the process inspection. We would probably be turning off -- we
will be turning off those other tasks so we take away the process
specificity. But now we go from tasks that took five or ten minutes
that may take inspectors an hour to complete because now they need
to look at the entire spectrum in order to make a systems
determination. So that's a little bit of the thinking about where we
are today and how we transition to where we're going tomorrow. The
uniformity -- again, I keep coming back is to the seven principles and
then we train our people to recognize what a critical controlling
point is. The plan must define what the critical limit is. And
therefore you now have your standards even though they're specific to
that plant. You have a standard that you would verify that critical
control point being in compliance by the critical limit established by
that plant. And we would target our inspections based on those.

MR. BILLY: How about training?

MR. SMITH: Training, again, what we're looking at training-wise
and, again, we're trying to use that just in time concept, that we
would have specific training on validation and verification and
enforcement activities for near term and we're looking right now at
at least -- at least a week that we'd be taking and developing training
and taking that to inspectors and veterinarians and supervisory
personnel. Then we'd see another training segment that would get
into the principles or philosophies of HACCP, the principles of HACCP.
That's where we'd be training them to do hazard identification,
critical control point identification, critical limit. Those particular
activities of how you build a plan and we would devote -- right now we're looking at at least a week to that activity. And then there's a third activity when the process actually comes on line. According to the schedule laid out in the regulation would be in-depth training on verification and validation activity and enforcement of those -- those activities. Along the lines of what we've been talking about here and so we'd have three specific training packages that one is completely devoted to near term and then two to HACCP and that's what we're looking at right now in order to equip our personnel to be able to act in a HACCP environment and then deal with this non-standardized that you discussed but by having those seven principles and having a critical control point, a critical limit, and monitoring activity and the records required, that, I believe, is where we get our standardization, at least to build an inspection system off of.

MR. OSER: I'd like to make one suggestion, Bill. It may not play too weak with some of the inspectors out there but because the training's going to be very difficult to accomplish and because you're putting an in-house inspector in a -- in what could be a precarious position. In other words, if a guy's out there and you're telling him he has to validate a hazard analysis, he has to validate a HACCP program, and the guy may not have had a whole lot of training in HACCP. It doesn't sound like the agency can afford perhaps to give him a whole lot. Rather than have him operate in that vein, have him, number one, verify that or validate that a hazard analysis does exist, number one; that a HACCP program does exist, number two; number three, make sure as they are currently doing and they're quite capable of doing, that these records are done, these checks are made. In other words,
what is said in the program is actually being done and give that 
inspector the opportunity to say I don't know if this thing is right or 
not right. I've got some questions about this plan. I would like to 
have it reviewed. And then have in your areas a team or a HACCP 
expert -- you know -- that word's been thrown around a lot -- or a 
HACCP coordinator or whatever that could then take a look at that 
cause I'm not sure we're being fair to all the guys in the field here to 
have them -- you know -- put a kind of stamp of approval on this 
thing and I would rather that you let that guy circulate around so 
everybody knows that sooner or later they can expect this guy in who 
will really do a validation on the HACCP plan and, number two, allow 
an inspector kind of the capability to say -- you know -- I'm not real 
familiar with this thing, I'd like somebody else to step in here and 
validate this.

It's a little bit like our labeling problems we've run into. You 
know -- you have the ability lots of time for an inspector to approve 
a label, it's within his right to do it, but a lot of them sometimes 
don't want to because they just don't feel they've had the training to 
do that. But in those situations -- you know -- we can send a label 
into Labeling in Washington. They do the approval of it. I think it 
gets you out of a sticky position here in terms of seven thousand or 
more guys in the field having to do this validation on a HACCP 
program that they may have been ill equipped to do.

MR. SMITH: We want to equip our people with our training in 
order to be able to do what we're asking them to do and I think it was 
very similar to what you just said what I said earlier -- that they are 
able to recognize that at least a valid analysis -- hazard analysis has
been done and that critical limits have been put in place to control those hazards and those type of activities. We do plan also -- we've been talking the in-plant role -- we do plan also to have teams going out and reviewing and doing in-depth validations of HACCP plans. But we don't know the frequency of that would occur and I also said earlier, I believe, that if an inspector does have a question on a critical control point or any that they will be able to get to supervision -- the area office -- and then from there their answers -- their questions will be answered which will include sending out a team to look at a plan or sending the plan in to have it looked at by our experts in Science and Technology. So that is our plans.

MR. TAYLOR: Let me just add, Alan, that one of the critical issues in our consideration of what the organizational structure of the agency should be as we go through the top to bottom exercise is how do we provide our front line inspectors with very immediate access to the scientific backing that they need to do their job inspecting in a HACCP environment and you'll take a look at the team report on organizational structure there's a discussion of options for doing that but to make HACCP work our inspectors have to be backed up in a number of critical ways but one is having very immediate access to the scientific expertise needed to make certain judgments in the plant.

MR. BILLY: Okay. I'm going to review my list. It's getting longer. We've got Pete and then Dave Butler, Joe, Gerald, Dane, another Joe. I don't know if that's the same Joe. Carole, Joe Pocius, Jim, Marvin, Jim Hankes, Angie, Tony, and did I miss anyone? Steve and Mike. Okay. All right, so Pete.
MR. PETERSON: My name is Pete Peterson. I'm associated with the National Meat Canners Association and I also run the Bunker Hill division of Castleberry Foods. We are meat canners. I concur with Dave's statement that we've been in HACCP since 1986. I date far back previous to that but after years of haggling with -- between the Department and the industry we recognized that early in the 80's that we had the potential of our consumers eating the most lethal organism known to mankind -- botulism. And that wasn't detected by looking at the exterior of the can cause it didn't cause any gas formation in there. So we got and sat down together and developed the canning regs which are twelve separate but interconnected sections that completely meet the USDA's HACCP regulatory strategy. We start with a definition. They get into containers and closures, thermal processing, processing schedules, operations in the plant, equipment and procedures for heat processing, processing and product records, record review and maintenance, process deviations, finished product inspection, personnel and training and a recall procedure. Our product does not leave our plants until all of these sections are met and reviewed. I would encourage all sides of this issue, including the Department, to go back and read 9 C.F.R. Chapter 3, Part 318. And Sub-parts G for meat and X for poultry. In addition to all of this, annually, our industry conduct or put on several better processing schools which are held at various universities around -- across the country. I know that USDA sends their inspectors to these better processing schools. We send our employees to these better programs. The instructors in these schools are from academia, from the industry, from Detroit associations, and it covers HACCP. In addition,
our companies on our staffs one or more process authorities so that we can handle and verify our own deviations. Our records are available to the plant inspector for review and are reviewed on a very routine basis. And, again, I say our product doesn't leave our plant until all of these control points have been met so you've got a blueprint to work with. I think -- you know -- you're haggling over how you're going to do this. Go back and read this blueprint. It will give you an excellent road map to go down the HACCP road by.

MR. BILLY: Dave Butler.

MR. BUTLER: Thank you, Mr. Billy. I've got so many things I'd like to address here but we've got a lot of top management here and -- you know -- inspection has come a long way in the last twenty five years and I'm an inspector from Missouri and I've been with them twenty some years and -- you know -- I have a sympathy for them. Their labor problem is hard to get. People just aren't like they used to be. Now if these top management officials here today would send their supervisors in the line here to this discussion I think it might be a little bit different but when you're working in one of these meat and poultry plants or whatever it might -- whatever type operation -- now your canning industry is a little bit different than your meat or poultry or your raw product or your immediate cooked. Now, I've been in so many plants and I can give you war stories here that just would set you on fire and -- you know -- top management has good ideas on what they want to do. These guys here probably do -- every one of them. But when they go back and it starts to funnel down into the chain of command down below it loses out. I mean there are people just aren't following up on what they're supposed to do and it isn't
just in the meat industry. It's in any type of operation you see. We
don't have the good labor force like we used to. People don't pay
attention. Of course, the older I get I find that's with me. But -- you
know -- I've worked in plants for many years that's got high dollar
stainless steel equipment. You know -- they spent a lot of money.
And the object of this -- money's the name of the game and if you
don't run your operation to make money you're going to be out on the
street. You can't afford not to. You've got to work with your
inspector and veterinarian in the plant. Now, we've got so many
places that they'll write their own PQC program, TQC program and
approve it and they cannot follow it. Now top management has --
they say yes, we want to follow it. But when you follow down to the
plant supervisor, the manager, the assistant manager, and the people
that's doing the actual operation in the field, they're not doing it. I
can give you many cases of cooked product. They'll drag it out of the
smoke ovens before time's up because they got to get "x" amount of
product run and they can't do it. It's got to come out under
temperature form unless you're there to catch them. Records are so
easy to falsify. It's -- and you can't catch them.

Now, I think before you go too far on your HACCP -- you know --
I think anything you do to make the inspector's job easier that's great.
We appreciate it. When we go out here and start writing up these
programs if they follow them that's great but they're not all going to
do it. They promise you the moon and you go out here and start
implementing and checking on the plants, they're losing out. And we
have -- I'll just give you incidents and I can tell you -- --. I was
working in a plant and I won't tell you what type of an operation or
what the product is. I saw maggots crawling on the floor and they
had a long conveyor like this running product down the line. Now they
had a stuffer to blow meat up on a probably ten or fifteen twenty foot
ceiling. A couple days prior to that maggots is working in the product
up on the ceiling and after a while they ate it up and started falling
on the conveyor but their employees didn't catch this and the USDA
inspector did. We've got plants where we have metal problems --
metal contamination. They didn't want to stop their operations. We
had to force them to do it. We've got plants that run spoiled products
in the coolers -- you know -- and we stopped their operation. Again,
how are they going to police themselves? I mean this sounds great
today and if followed it would be great and a lot of plants will. I
mean not all plants -- but I think every top management has good
intentions but when you get down to the lower ranks and the working
force out there communication is a problem. We have so many
different nationalities working. They cannot speak English in these
plants and they're dealing with a food product. And really whenever -
- if it's an inspector -- if he started working on a product on the line
you forget about it being a food product. And it's also awful easy to
do. And I think that -- I think Alan up here touched on inspection --
on the training. I'm sure that -- you know -- a week's adequate
training is for most inspectors -- I mean we've been in so many
plants out there that the TQC people have had their problem of
management telling them to back off of their job and not be so strict.
You know -- they can't tie up the product. But you got to work this
out some way.

MR. TAYLOR: A couple of comments in response, Dave. The
reforms we're talking about, including adoption of HACCP, but also the manner in which we're looking to change the role of inspection are together intended to enhance the capacity of our inspectors to insure that plants are carrying out their responsibility. And, again, if in the end we're not enhancing the capacity of inspectors to insure that plants are meeting their responsibility we won't have done what we set out to do. And that does mean some changes in the way in which, for example, in the sanitation area we use our enforcement tools -- our authorities -- because we want to shift to a mode in which the failure of a plant to meet its responsibility as defined in its SOP will have implications for whether that plant will be able to operate and whether we will apply a very substantial legal tools we've got to suspend or withdraw inspection in plants who aren't doing their job on a consistent basis as defined in tools such as a sanitation SOP so accountability means consequences if plants are not doing the job that they laid out. And, again, using the sanitation SOP example, as the plan for meeting the aspect of their responsibilities so it is a matter of enhancement but more clearly defining responsibility and then enhancing our responsibility to hold plants accountable for meeting their responsibility. The objective is enhancement and that's a test that I think everybody needs to hold this initiative to. If it's not enhancing our ability to insure that plants are meeting their clear responsibilities in areas such as sanitation then it's not what we set out to do.

MR. BUTLER: Well, I guess one of the things I was talking about was -- you know -- when they write up the program yes, if everybody follows it I mean that's fine but it's going to be harder for them to
follow it, I think, with this.

MR. TAYLOR: Under this they will have enhanced incentives to follow it just by the way in which we discussed -- implementing the SOP's. There will be consequences beyond just having to clean up the equipment, there will be consequences for not carrying out the responsibility that a plant has in the case of sanitation of SOP's to carry that out in a consistent and effective way.

MR. DUFF: Joe Duff. I just wanted to -- Joe Duff again. I just wanted to touch on a couple of points that I was really bothered by in Mr. Muskat's comments about teams of inspectors going around. A few years ago when it came out it smelled like DI and it smells like DI today. It was a bad idea then, it's a bad idea tomorrow, and it's a bad idea ten years from now. DI is just not an effective tool for inspection.

The other comment relating back to what the girl was talking about when there's a violation of a CCP. What no one has stated is what happens to that product? Do you want it to continue on but you don't want us to do anything to it, just let this product that has an obvious violation going out into the consuming public and I just have a problem with that. I have a very serious problem with that. I was wondering if someone would want to comment.

MR. POCIUS: That's what I was going to comment on if I could. Thank you. I cut you off there Dane. Two things that I did want to mention and one was that it seemed to me at this end of the table that we hadn't really come to closure on what happens when you fail a CCP and from what I heard from Caroline it was some least some misunderstanding of how that works and I hope I clear it up and don't
up a bee's nest instead but when you fail a CCP, in fact, that may
result in a line stoppage. You're right. Because of the consequences
of failing a CCP and the health thing, that doesn't mean that the
HACCP program failed and I think that's what Bill was talking about
and there's a big difference. It doesn't mean that the program goes
through revalidation. It means that a corrective action has to be
taken. You also have to control that product and the product should be
evaluated by a process authority to find out how badly the
consequences of failing that critical limit are. Is it, in fact, failed to
the point of being an actual public health risk or can you release it or
can you rework it? Okay. I mean those things weren't -- I don't think
-- made very clear during the previous conversation.

There's one other thing I want to touch on as long as I have the
mike and that was the description of minimum CCP's and
identification of minimum CCP's. That may -- again, I'm with the
National Turkey Federation. In our industry we have large companies,
we have mid-size, we have small companies and the mid-size and
small companies have all pretty much said the same thing and we
can't forget them in this that they need some help here. They would
like to have some of these things identified but there's a difference
between identifying these things, putting them into guidelines, and
mandating them. We would all disagree very strongly if you were to
mandate them because then the purpose and the flexibility of HACCP
is defeated. On the other hand, if you were to put those into
guidelines and supply those guidelines to the industry they may help,
particularly the smaller companies get along, but one problem that I
have -- that we've seen with guidelines and I'll give an example --
the directives on basting poultry. There are examples that are given
in that directive that are interpreted in the field as the bible and
that's the problem with guidelines. Sometimes after time goes by
they're interpreted hard and fast rather than as suggestions so just to
keep in mind should you go that way as well.

MR. MORRISON: I'd like to make one comment. Something that
another trade organization did together -- you talk about -- you know
-- Turkey Federation having large and small and medium sized
companies. Well, the National Meat Canners Association has very
large companies such as Hormel and we have very small companies.
What we did when these regulations came out in the mid-80's we
would, through the organization, help small companies develop them.
We did it with them as an association. We didn't ask the USDA to do
that. We did them. And I would submit that maybe the Turkey
Federation ought to do that.

MR. POCIUS: In fact we have. Back in 1991 we developed a
model for the turkey industry and distributed it back then. But for us,
there is a perceived difference between the trade association and
regulatory and if there is a possibility that there will be regulatory
requirements our members will perceive that differently from the
voluntary system which we've developed. So, coming from the agency,
a guideline might be helpful.

MR. SMITH: I just want to follow up on the enforcement. To talk
about the CCP failure, one of the critical components of a HACCP plan
is to identify the corrective and preventive action when a CCP is not
met. What we are expecting is the plant -- if we had a cooking
failure, as we said there, and they rolled it into the cooler they would
then, as a follow up to that, to a disposition of that product would get an analysis done probably from a processing authority to go back to meet or equal or exceed what the critical limit was originally established for. So if you had a cooking temperature established for a 5-D reduction of 015787 and a 7-D reduction of salmonella and the product did not meet that then it would be the responsibility of the plant to have that evaluated and determine how that critical limit can be met before that product can go out. That is the expectation that the plant will do that. If they do that, and this is a little different for inspection but it's part of the culture shift -- if they do all that and they determine either through either recooking or the cook that it did receive was rigorous enough to meet the critical limit, that that product can be shipped without FSIS's blessing of whether that can take place or not. We will verify that corrective action through our verification process such that we would expect then to see the analysis by the processing authority that said that that did result in a 5-D and a 7-D kill and that the decision could be made to ship it. It's a little different mind shift.

Now, if the plant does not do that then -- and we need to take control of the product for failure then we have a systems failure. Not only is the product retained but that process is suspended. And the HACCP plan is invalid at that point because we have had a system failure. So we need to understand that we have a responsibility to let plants take corrective action when a limit is not met and as long as they're doing that and we're verifying that then we have a system that's working. However, as Mike was saying, if we have system failure, then we are going to use our authorities which would be as
proposed -- suspension -- and we initiate the rules of practice of what goes along with that towards withdrawal.

Same thing in sanitation SOP's. If we have repeated occurrences of direct product contamination we will be training our inspectors in the procedure that we will suspend the operation when we have repeated instances of direct product contamination. We will be verbally notifying the plant of that. The inspector will be calling the area office and what we're planning on at this point is bringing compliance in to help document that case and that initiates an administrative action and that is our plan. That is a lot different than the behavior that we're doing now. So while we're saying we need to let the plants take responsibility for running their systems and we need to be able to verify that that's going on. The failure of those systems to protect the public will result in enforcement actions which we have available to us now we would be taking. And so those are the things when I was talking earlier -- validation, verification, and enforcement -- that we would be training our inspectors in that enforcement mode.

MR. BILLY: I think what I'm going to do is -- I've tested your patience a little -- I think we'll have about a fifteen minute break, not a half hour, fifteen minutes so be back at about ten after four. Also, I have an announcement. The paper -- the briefing paper for tomorrow should be out on the table and there's also going to be a second paper that will be there about four o'clock so you might want to wait till the tail end of the break and you'll be able to get both at once. They're related to each other in terms of the -- you know -- the basis for some of the discussion on issues tomorrow. Be back at ten
after four.

(A brief recess was taken)

MR. BILLY: I'd like to get started again. Deputy Secretary Richard Rominger has joined us and he'd like to say a few remarks before we get started back on the program.

MR. ROMINGER: Thank you, Tom. I wanted to express my interest in this process that is taking place here. I understand that Secretary Glickman was here this morning and spent some time with you. Unfortunately, we can't spend time here for all of your discussion but this is a high priority for this administration, for this Department, and I just want to thank all of you for participating in it and making sure that this dialogue happens. So I am just here to listen to some of the dialogue that's taking place and make sure that we are getting a good dialogue and getting the input we're going to need to make sure that we have a HACCP program that works when we get done. So carry on.

MR. BILLY: Thank you very much. I wanted to remind everyone -- I mentioned it before the break but there are two papers out on the table to my right. The paper titled Regulatory Shift to Performance Standards - Lerring and an accompanying piece titled Backgrounder Regulatory Reform Initiatives of the Food Safety and Inspection Service. And I hope you all got it. If you haven't there's more out there and this would be good reading material prior to tomorrow's session.

One of the questions that occurred to Mike Taylor and myself at the beginning of the break was whether -- you know -- there are some groups that we haven't heard from yet in terms of this issue of
inspection under HACCP and the role of inspectors and that would be particularly those people that represent the smaller plants. And so I wanted to make sure that they were felt that these discussions were covering their concerns. I know they raised some concerns in their comments in this area. This was a particular area of emphasis so -- you know -- please be sure to grab a microphone and raise your concerns or if they haven't been addressed or there's a particular angle that you want covered that hasn't been addressed to date it's real important for us to hear what your concerns are. So I just wanted to make sure that that would happen to the extent it needs to.

With that I also want to remind people, look back on the agenda for this afternoon's session that is covering the changing of the relationship between FSIS and the plants, including the inspection approach which we've talked about some of the billeted items on this agenda and then the changing roles of inspectors under HACCP. And, again, we've covered a couple of the billeted items. I'm going to leave it to you. If you feel there's a particular item here that hasn't been addressed yet that you want to get on the table for discussion and have a discussion about I'm going to hold you responsible for doing that. These are items that either we identified or you identified at the scoping session where things that were reflected in comments. I don't want to derail the current discussion but we're very open to making sure that we cover any of these other points that haven't been addressed to date.

Okay. The next person on my list is Gerald.

MR. LORGE: My name is Gerald Lorge. I'm an inspector with FSIS. My biggest concern with HACCP is that if we're going to have an
opportunity to look at the product. We talk here about checking
establishments, documentations, standard operating procedures,
besides performing our PBIS tasks and the other numerous daily
papers that we have and it seems like we're just getting away from
what we are really sent there to do which is to look at the product.
And we're concerned that if this -- if HACCP is not turned into a
vehicle to start less than continuous inspection or carcass by carcass
inspection in the way where in something like in excess of nine
hundred inspectors short in personnel now and doubling and tripling
an assignments and barely can make the mandate -- -- every
assignment that we get and some of them don't get visited every day
and we just don't want to see HACCP as a way of justifying or
eliminating the continuous inspection and that's all I have to say.

MR. SMITH: Okay. I'll address the -- are we going to be able to
touch the product? That is part of plant verification. I mean our
verification of what the plant is doing so if that is part of a critical
control point of taking a temperature that we would be physically
taking temperatures to verify some CCP's. That is sodium nitrate
amounts is a critical control point as far as doing formulation, as far
as chemical hazards, then we would still be calculating and observing
those as a verification activity. So it doesn't eliminate what we're
doing. It just changes how and when we do it and how many points
along the way we use in order to determine whether a system is in
place or not. But we're not going to get away -- totally away from
not dealing with product.

MR. LORGE: I'm more or less talking about the additional burden
already put on the inspection staff by shortage of help and adding in
addition to that the HACCP concept with checking these tasks, the paperwork management, and that type. We can't meet all these. We're barely meeting our minimum requirements now. And is it really going to help the system? Really all we're looking for is microbial testing and checking for the invisible pathogen. We already have regulatory enforcement in place in the progressive enforcement action and I don't see the reason for adding all this other task when we really just need the microbial testing.

MR. TAYLOR: Let me just make a comment on that. One of the advantages that we see in HACCP is that it is a tool for focusing both plant effort and inspection effort on the foods and the process they're most critical for the safety of the product and as a framework for both producing safe food and then providing inspectional oversight for, say, food production processes, HACCP has that critical advantage and it also by virtue of the record keeping aspect and the systematic process control aspect has the advantage of really expanding an inspector's ability to assess whether a plant is operating under control with respect to those critical safety factors. But HACCP and the oversight of HACCP in terms of inspecting records and so forth is not a substitute for in-plant observations of product, in-plant observations of activities being carried out by the company in the plant, and certainly not only not a replacement for microbial testing but I think we envision in a regime in which we are moving towards performance standards for harmful bacteria on product that we don't critically have there will be no doubt an enhancement of the role of product sampling and microbial testing by FSIS as part of its oversight functions. So, again, I think it is a mistake in
understanding what HACCP is about to think of it as a substitute for in-plant inspection. It is a framework for very fundamentally changing but enhancing, not changing and diminishing, changing and enhancing the contribution that each inspector can make to insuring the safety of the product. So it's not by design a substitute for it. It's an enhancement of that in-plant inspection role and definitely not a substitute for looking at product. It's just that we've got to focus our efforts, just as the plant has to focus our efforts, on the most critical foods in the process from a food safety standpoint. That's the organizing power of HACCP, if you will, from an inspection standpoint and that's why it should serve as an enhancement.

MR. JAN: Lee Jan, National Association of State Meat and Food Inspection Directors. Regarding Inspector Lorge's comments about concerns with HACCP taking away or going to where an inspector doesn't have to be in a plant every day, I think that HACCP is the system that will allow that and with today's shrinking budgets and hopefully growing industry if you mandate daily inspection and HACCP as well you're going to have to violate or not meet your own requirements for daily inspection. You're going to have to get away from daily inspection. And Mr. Allen asked that or suggested that inspection be a set -- a new set of eyes or third set of eyes because their people tend to get barn blind to use his terminology because they see it every day. If we have an inspector in the plant every day they can get just as barn blind so I think you can have a better inspection with the HACCP that is a functioning HACCP, it's a program of the plant. We do have those verification tests and record verifications that prove or verify that the HACCP is working but we
cannot continue to say or continue to go with -- we have to be in the
plants every day. You're already not doing that. The rules are that you
have to be in there every day but that's not happening. I've heard that
said several times today by the inspectors that they can't be in the
plants every day so we need to get away and accept that and move on
to let HACCP take its role and as far as the small plants as well as
large plants need to be in this mode to go to HACCP. I do want to
bring out that the small plants will need some extra help or be
allowed to get some kind of help where they don't have a quality
control staff. Their only quality control staff is the manager or the
plant owner and I think there's a role for state agencies, whether they
be health departments or like in our case, a state meat and poultry
inspection program, that can be there to give them not a helping hand
but be there to kind of help guide them to developing their own HACCP
plans. And I think from a broad picture those big plants -- we've
heard from Excell and the Canners and Hormel -- a lot of them have
HACCP plans now. They all belong to our organizations. If those
organizations would get together or individual organizations work
with the experts at FSIS to develop HACCP plans guidelines -- not
HACCP plans but HACCP plan guidelines that have input from both the
experience of industry and the expertise of inspection or regulatory
expertise and come up with plans that can be easily accepted by
regulatory, even though they're primarily developed by the industry.
And I think that would be a great help to develop those type of
guidelines for small plants. And I think just because they're small
doesn't mean they can't go HACCP. I think they should go HACCP. They
just need those little extra help. Thank you.
MR. BILLY: Dane?

MR. BERNARD: Thank you, Mr. Chairman. I think the tenor of the discussion has changed since I held my banner up but never being at a loss --

UNIDENTIFIED VOICE: You're not going to say anything?

MR. BERNARD: No, sir, it does not. You're not quite that lucky at this hour of the day.

Let me go back to when I did hold my banner up just shortly after Mr. Smith's presentation and let me recapture that if I could. I think in terms of the roles of the agency and the roles of the inspector I think the concepts that you explained to us, Bill, were exactly on target -- verification, validation. Beyond that, and it's not an unusual state for me, I got a bit confused in your presentation because you seem to be mixing in critical control points. You seem to be mixing in sanitation SOP's and the reaction to violations of those and I think it got a bit confusing so I would like to encourage you to make sure that we get that clarified in terms of reactions to a violation of a critical control point versus how a sanitation violation, which does not directly affect the safety of the product, is to be handled so that those situations are indeed clarified.

There was also discussion of the role of generic HACCP plans and Lee said it very well. There is a role and Mr. Prucha said it very well as well. There is a role for generics. I think by and large the industry wants to have the latitude to develop its own HACCP plans which reflect the particular needs of a product and plant and line. Generics can serve well as models for use in training and can be adapted by smaller operations who don't have the capabilities of
conducting hazard analyses but these should not become standards just because they're developed by the agency and put on the table by the agency. Every company's HACCP plan should be viewed in the validation process on its own merits. There was also talk about the shift that needs to take place and it has been said but I want to clarify that the shift is not only in the agency. There's shift needed within the industry. We here in Washington tend to go quickly from the objectives and we get lost in the details. Keep your eyes on the objectives. The objective of HACCP is to come up with a safety management plan which is then translated very quickly to the people who have the most direct control over the safety of the foods we produce and that's the people on the line -- the operating people. That is done and you've heard many times from several voices here of people with HACCP experience in plant. It's done through cooperation. It's done through training. And the same dynamics must be embraced by the agency. It's got to get down to the field and operations level or we're not going to get the benefit that we all strive for with this particular system. Is it easy? No. If it were easy we wouldn't have this room full of people here discussing it. Is it going to take time, is it going to take a lot of discussion? Yes. It's not time to give it up and just go to finished product testing as the criteria by which we'll judge the safety of the product. And Mr. Taylor said very well that what we hope to accomplish in HACCP is to enhance the safety of the foods by having better control over the operations. If we inspect products, if we test products, we know that the product we test has a certain characteristic. That may or may not translate to that same characteristic in every unit of product. If we do our homework
correctly and put together good HACCP plans underlying the operative word HACCP plans we will have greater confidence in every unit of product that comes out of production line and that is the ultimate objective is to gain that greater confidence in every unit produced. Thank you, Mr. Chairman.

MR. BILLY: Joe Pembroke.

MR. PEMBROKE: Thank you, Mr. Chairman. I'd just like to expand on a few comments that we've been hearing around this table. First of all, I'd like to say that I've probably served the Department of Agriculture for seven and a half years in the regulatory division and while I was there I was assisting and drafting many regulations promulgated under the Meat and Inspection Act and Poultry Product Inspection Act and, in fact, I went toe to toe with many of the attorneys in this room withdrawing inspection for some of the plants. I now work for a large food company in the United States which has divisions which include some of the largest processing meat and pizza companies and I'm also here as a delegate for AFIE which is the American Frozen Food Institute. It's a national trade organization representing frozen food processors, suppliers, and marketers. There is a 560 member company and accounts for over ninety percent of the frozen food products in production in the United States. I was honored to serve here and I have the utmost respect for both the compliance and the inspection staff. However, we need to see why we're here in HACCP. It's a distinction that I think we are not making between slaughter and processing. And HACCP gives us the ability to recognize this distinction and to allocate the agency's resources. I agree with the agency that no formal prior approval acceptance of an
establishment's HACCP plan by FSIS is needed. In fact, when I look at some of our Tombstone Pizza Companies' inspectors are only in our plant on average -- you know -- two or three hours a day. I don't think the likelihood of producing an unwholesome product in the five or ten hours that the inspector isn't in the plant there is any greater. We have PQC, TQC programs that are precursors to HACCP and I think Dale and other people said that when you evaluate a HACCP plan it's a process over time. You can't just go in and check it off and say this piece of paper proves that it's working. You have to look at it over time. HACCP plans are dynamic documents and I think we all agree that they're subject to modification and improvements. I think if we require a prior approval or requirement for such an approval it would inhibit or slow down this process and prevent industry from coming up with continual improvement.

Now, dealing with small manufacturers, I agree that some people may not be as experienced with HACCP or HACCP plans and I think they should consult and they should ask and should be encouraged to consult with the USDA. However, if we're going to design and implement the plan and under the plan is a HACCP plan is a responsibility of the company and I think, therefore, if we require an inspector prior approval to look at these plans we're falling back into the old system where the inspector then becomes the QA person for that plant and that's what we have to avoid. And I think that's what our industry's perspective is on what HACCP means to us. Thank you.

MR. BILLY: Carol.

MS. FOREMAN: Thank you. It's clear that all of our -- this is Carol Tucker Foreman again. It's clear that Joe, and Dane, and I all
flipped our flags out at about the same time. I put mine out because
Alan Oser was talking about the problem being that HACCP is a non-
standard procedure by its nature and it's hard to impose a
standardized system on it and, Bill, I wanted to try to tee through
something with you.

If we're looking for a non-standard flexible way to get to a
product that does meet a standard, isn't that what we're doing here?
They want to let each plant do its thing as long as what comes out at
the end of the line meets the safety requirements so that it's
acceptable to be sold to the public.

MR. SMITH: Yes.

MS. FOREMAN: Okay. So, I know there's a version to end product
testing here but it strikes me that at some level the end product
testing is the mechanism by which the plant is allowed to put its
critical control points together in the way that works best for that
plant because you can demonstrate at the end that you have generated
a product that meets that safety standard so I have a couple of
questions, Bill -- three.

Let me use cooked sausage. You have a kill step there. Will a
plant have to provide to USDA as part of its HACCP plan end product
sampling data on end product sampling that shows that the product is,
in fact, free of salmonella?

MR. SMITH: We would envision that that would be part of plant
verification activity. That is one way of verifying the effectiveness
of your HACCP plan would be testing to see if there's a kill step that
the product is pathogen free. So that's one possibility of doing that,
yes.
MS. FOREMAN: Is there any other way to do that?

MR. BILLY: It may be useful to have Pat Stolfa talk a little bit more about the role of product testing in first developing a plan and then validating a plan and then on-going verification of the plan because I think that would be real relevant Carol.

MS. FOREMAN: Yeah. That would be very helpful too.

MS. STOLFA: I think that actually some of the comments made earlier today by people who have been involved with the canning industry over the years might be relevant here. I'm sure that at the time that the critical control points, which really form the basis for our regulation as well as the FDA regulations of low acid canned foods, at the time that those were being developed and the determinations needed to be made about whether or not those were the correct critical control points, that indeed product testing was an important part of the determining that. And I'm sure that early in the process the notion of product testing was something that needed to be done on a far more frequent basis than is common in the canning industry today where I don't believe that end product testing is in any sense a routine. However, if significant changes were to made in the canning regulations or in any particular process, and I think perhaps cooked sausages too -- or fermented sausages have a lesson to teach us, and that is that from time to time we may want to be going back and validating processes and certainly I think companies want to do that. That is in the interest of companies as much as it is in the interest of government. As information changes, as we learn new things about whether -- you know -- we have emerging pathogens for one thing and I think that this process of validation using micro
testing is something that has occurred as we've seen HACCP used for
control of various processes and it's something that we can expect
would be a part of processes that would be coming under HACCP at
this point.

MS. FOREMAN: So an inspector working in a plant with a HACCP
program might regularly ask to examine records that demonstrated
that some samples have been taken on a cooked sausage to make sure
that it was salmonella free?

MR. SMITH: If that's part of their plant verification activity,
yes, that would be not only for pathogens but company's might be
doing it for total plate counts for any number of -- of areas on the
micro sampling that those records, if they're used for plant
verification activity and must be completed as a criteria for
shipment, then that would be a regularly reviewed and audited record
by inspectors.

MS. FOREMAN: Could you have a cooked sausage HACCP plan that
was not -- had never been subjected to sampling for effectiveness in
killing bacteria?

UNIDENTIFIED VOICE: Could you restate your question?

MS. FOREMAN: Could you have a generic HACCP plan or a HACCP
plan in a plant approved by USDA where that plan -- the products of
that plan had never been subjected to sampling for bacterial content?
This is cooked sausage I'm talking about.

MR. SMITH: I can't say with a hundred percent certainty that
every cooked sausage plant would or would not as part of their --
their verification. What I can say though in the hazard analysis they
would have to determine a process rigorous enough to insure that
there is a -- the kill step is effective.

MS. FOREMAN: How do you know the kill step's effective?

MR. SMITH: Either -- either through -- again, either -- most of them would be doing sampling to verify that. There also is literature in studies that support that. There is also the agency will be conducting verification which includes sampling just like we're doing today. We are sampling cooked sausage out there today and roast beef and we would continue. So all of that activity would be going on.

MS. FOREMAN: Okay. You've actually answered my third question which is, would FSIS continue to sample to verify? I do have a little bit of a problem with the notion that somebody has a HACCP plan that was put together based on a hazard analysis and an assumption that's based on any study or any data applied any place except that product in that plant. Whether or not it works, I thought this was the virtue of HACCP that it is a non-standard flexible approach where each plant gets to do its way. If that gets turned around and you say but if you go through step one, two, and three you never have to check it because we assume. That goes back to being an act of faith that I'm prepared to accept yet. But it does strike me that what you have here is when plants can sample and show that they've met this performance standard that that should enhance everybody's faith in the steps that preceded it, especially in those processes where there's a kill step. Then if you do this on some regular basis you've, seems to me, got a continuing ability to assure yourselves and the public that your HACCP plan is actually effective. Thank you.

MR. TAYLOR: Let me just make an observation again, sort of indication of where our current thinking is. I actually think when you
-- when you see the approach that we're considering in adopting performance standards as an option for cooked product. In the backgrounder that we handed out today gives you a brief description of that planned proposal you'll see what I mean about our current thinking. But we have to distinguish between the role that testing might play in the validation of a -- of a plan or a process with -- which is a kill step plan or process and the testing that might be required and verification of that on an on-going basis and operation. And I think it's -- well, theoretically there may be some -- I suppose some plans or some set of plans or controls that are so thoroughly tested and established in the literature that there -- you can prophesize perhaps -- theorize that you wouldn't in a particular plant setting need to do microbial testing to validate in that plant. It's very hard to imagine that you would -- you could appropriately validate the operation of a kill step process in a particular plant without some testing as part of that validation.

Once you have validated a kill step process in a plant, however, and you have some clear critical control points or processing parameters that have been validated to work, then it's a different question of what the role of microbial testing would be on an on-going basis to verify that's operating. I think what we understand is that, using the canned product example, that, again, my understanding certainly is that on-going -- you know -- verification testing of finished product that's been through a well documented and validated -- you know -- kill process to produce a canned product is not the general rule but I think if you look back you'd see that the development in validation of processes -- you know -- there's
definitely a role for microbial testing.

But the processed product arena where kill steps are involved do present a particular set of -- a distinct set of issues about the role of testing from raw products obviously.

MR. MORRISON: I can expand on that. Dave Morrison again from the National Meat Canners Association. Specifically, there's some very valid rules in canning. You have to go through on a very routine basis of verifying that a retort, for instance, that the heat distribution is the same year to year, that it hasn't changed because you had corrosion in pipes or something or you changed your separator plates and maybe they went from an inch to a half inch. Any formulation change that you do. You add a new spice or something to the -- to the product you have to redo all of that and you have the incubation step, of course, that is a verification. Very few people will do on a canned product an actual bacteriological step as a verification but you have other things that you have to check like the incubation and a sampling program to look and see that those products are safe and valid.

MS. FOREMAN: Is this something you don’t do on a regular basis or you never do?

MR. PETERSON: Which?

MS. FOREMAN: That it popped a can out and analyzed whether or not it's what you think it is.

MR. PETERSON: That's done. Most plants have what we call a cutting session every day where they bring their employees in and they look at those products every single day.

MS. FOREMAN: That's exactly what I wanted to know. Great.
MR. PETERSON: Well, she didn't ask me about micro that time. She asked me if we looked at the problem.

MS. FOREMAN: Well, I assumed that that included some --

MR. PETERSON: Micro every day -- we don't do micro every day but we look at a sample of incubated product from every day's production -- usually about a five percent sample.

MS. MACKLOW: When you say look at, what do you mean look at?

MR. PETERSON: We examine it can by can for seaming defects, for any kind of outward and visible sign through the years that would indicate that we have a problem.

MS. FOREMAN: How often would you do a micro check on it?

MR. PETERSON: Only if we had a process deviation that said needed verification or if we found a -- some unidentifiable sweller then we would do a test on that product to find out what it was and possibly what had happened. We'd go back through the records also and see if we had a what could have caused this.

MS. FOREMAN: Thank you. Could I ask another question? At Oscar Meyer, on that wonderful mile long hot dog chain you got out there, you all test that for bacteria, you do regular samples?

MS. SIEMENS: This is Angie Siemens with Oscar Meyer. In actuality we do product testing. What we do is equipment testing relative to sanitation, pre-op, operational equipment testing, we do shelf life samples where we run samples but we do not do pathogen testing. Let me back it up and say pathogen testing on our product to insure our products have done. But we are very committed to integrated validity relative to understanding some of the basics in the science transfer that has come out from the studies showing
lethality curves and our time and temperatures are highly regulated. We have HACCP plans in every one of our processes now that are based on the science dealing with a lot of the integrated lethality premise and the science based around what a lot of the roast beef regulations were determined around. But we are not doing consistent pathogen product testing to verify our programs. We feel that using the HACCP plans, and Dane alluded to this before, that we are comfortable that we have validated the current plans that we have and continue to work with those plans and are not, unless there's a deviation that comes up that was mentioned before, we're not going to go back and do a consistent product testing.

MS. FOREMAN: Did you do it to validate the plan initially?

MS. SIEMENS: We've not done product pathogen testing on product testing. We've used our experience based on what we have seen in the past of cooking temperatures plus regulatory cooking temperatures because there are regulations in place for final product temperatures that have assured safety been based on a long history of --

MS. FOREMAN: You never go look at a hot dog?

MS. SIEMENS: No, no, I didn't say we didn't look at a hot dog. We don't pathogen test each hot dog or continue to come back with it because we have faith in the science and our comfortable with the science.

MS. FOREMAN: It strikes me that the LA Times took some of your hot dogs out and tested them and found some salmonella and listeria in them.

MS. MACKLOW: Probably not in them, maybe on them, because
the issue becomes one of recontamination because of different steps
-- -- to make --

MR. SMITH: Just to clarify. What kind -- how did you arrive at
your critical limit?

MS. SIEMENS: The critical limits that we established within our
plant. Critical limits relative to temperature. Let me tie in with
that because that's what we're dealing with -- basically the final --
and I have to be careful to keep a job when I get home on some things
-- but critical limits are based on -- our poultry products, of course,
you've got the 155 and 160 mandated in the regulations. That is a
critical limit over time the government has established in terms of
being a final processed limit. We actually cook to higher
temperatures, not for safety reasons but for quality reasons. So not
only have we built in a factor, and I think many processors around
this room would say that we are not cooking probably to the absolute
minimum of many of the regulations which have already been
determined to have safety factors in them, we are cooking to higher
temperatures for many quality reasons. And it depends. Not every hot
dog is processed exactly the same and we've not got the same end
point temperature nor humidity, etc. in all those factors -- time and
temperature, humidity that go into those for each and every process
that we have. Because we've gone through and we're comfortable, not
only with the safety of the product, but we also have to examine in
our situation the quality of the product as well. And, again, the thing
that is -- we're just not starting to cook hot dogs. We may be just
instituting a HACCP program which is a different way of examining
the safety but we've been producing safe products for decades and we
base ourselves off of that history on the temperatures that we
develop and that's where I think we get into, based on the history of
it, we feel comfortable. We don't have to validate over and over again
that our processes are safe. It's a continuing process. It's been a
learning experience, etc.

MS. FOREMAN: I'm just curious why you wouldn't from time to
time look at one to see if there are bacteria in it, if there's
salmonella or listeria in it. Did you end up in court over it?

MS. SIEMENS: No, we don't. We --

MS. FOREMAN: No. I mean would you if there's some reason not
to?

UNIDENTIFIED VOICE: I think she said it's not there.

MS. SIEMENS: We're comfortable with our processes. We're not
saying the process --

MS. FOREMAN: I'm not a scientist but it's not what I learned of
scientific method when I was in school, with all due respect.

MR. OLSON: Excuse me. I'm Phillip Olson. I'm from Olson, Frank,
and Weda, counsel for the National Meat Association. Seems to me
there are two different hazards here. One hazard is the risk that
there will be salmonella in a cooked sausage when it comes out of the
cook house and what I'm hearing people say here is that if the time
and temperature requirements are met it's like meeting the time and
temperature requirements on something at home. That there's certain
levels in which there's a built-in safety factor. There's another -- so
that's one thing in a plan. Do you -- is that something -- what is your
control for that and it may well be to show that you cook to a certain
temperature for a certain time.
Now, the other substance you're mentioning -- the other bacteria is listeria. Listeria is a re-contamination and so there I think you'll find companies in their HACCP plans will address that differently, either by sanitation measures or environmental sampling, but that's not in the product so it comes down to HACCP plans meeting the individual identified hazards and then have appropriate response.

MS. FOREMAN: Let me limit it to salmonella. I'm just curious about why a company would never take a product and run a sample on it just to be sure and I still don't understand it.

MS. MACKLOW: There's no -- finished temperature has killed it. It has more than killed it.

MS. FOREMAN: That's funny. Where I come from a scientific method says that at least initially to verify that you have to test to find out if your theory is correct.

MR. LOCHNER: What we do on occasion -- there's different philosophies. This is Jim Lochner of AVP. Some people do and some people don't. Now, depends upon the history and the confidence you have with your history and I do believe a long time ago that all processed meat manufacturers before the legal liability issues in a classification of adulterance have built up histories on time temperatures with various processes. Now, personally, I do take occasional samples for salmonella on cooked items. And I hold that lot, don't release it until I have a confirmed negative result. So, do that on a routine, not every day, not every batch, but on a periodic basis it comes up. Therefore, I have confidence that the HACCP plan - - to me, that's just a built-in check. Now you can do that. That's your
option and I don't know if we're after on this set of questions should
that be -- I think your question, Carol, should that be a matter of
routine or should that be an assumed, if I'm asking your question
right.

MS. FOREMAN: I thought that it was the way in which you could
reassure both the inspection staff and the public that a plant has the
flexibility to create a HACCP program that meets the specific needs
of that plant and that product and, yet, meets the need as well of the
public for safe product and that it requires no judgment on anybody's
part because you have used science. You have taken a sample and
tested it.

MR. LOCHNER: You validated your process on a routine basis.

MS. FOREMAN: Right.

MR. LOCHNER: And I think -- I think the question I would have
back to FSIS, would that be an automatic check point to say that
you're validating your HACCP plan? We're dealing with cooked. I'd
like to deal with raw at some point but I --

MS. FOREMAN: That's tomorrow, Jim.

MR. LOCHNER: I think we ought to deal with it a little bit today
but I can wait till tomorrow.

MS. FOREMAN: But that's a very good question. Thank you. That's
where I was going.

MR. BILLY: Dane?

MS. FOREMAN: I thought Jim had a question on the floor.

MR. LOCHNER: I had one but it's going to deal with fresh.

MR. SMITH: On cooked product we are sampling today for
salmonella, listeria, and E. Coli 015787, not in cooked products, but
in the raw. Those sampling plans or programs will still be in effect. And they would be a check on those programs.

MS. FOREMAN: But would data that they are -- that they've got a cook step and they've sampled the product and it is free of salmonella be a validating point for the HACCP plan even if other parts of the HACCP plan may be -- didn't look like anything you'd ever seen before? Okay. Thank you.

MR. BILLY: Dane?

MR. BERNARD: Sounds like we've got some disagreement here. I really don't think we have all that much disagreement if we understand the dynamic of process establishment. Angie has given kind of a thumbnail sketch of all of this. There is, and having gone through this a number of times both on meat and poultry products which must be stored refrigerated as well as canned foods, we have a long history of going in and setting up and validating processes. You can show me a book of data of salmonella testing on your hot dogs. That to me does not tell me whether an operation is under control. You can show me zeros ad incron item. That means you've done a lot of testing. That does not mean to me your operation's under control and give me the kind of confidence I want as a process authority that you're doing your job.

Angie's process as well as any other process that you set up on that basis starts with microbiological testing. It's there. It's kind of like that commercial for spaghetti sauce. It's in there. Doesn't mean you have to test every lot but it starts with microbiological testing of a scientific nature to find out what time and temperature it takes to kill the target population of bugs. That's pathogen, that's spoilage
organisms, that's things that limits your shelf life and we take all of
that as we have done over and over in cooked sausages and say, that's
our target. We need to achieve "x" many minutes at "y" temperature to
have faith that this product is going to be safe when it comes out of
the cooker. Then we take that to the plant and we say, okay, here is
the cooked device. What are the variabilities in that cooker? Can we
count on every 2,000 pounds, every pound of that 2,000 pound batch
that comes out of that cooker receiving at least that cook as a
minimum and how do we set it up and how do we validate that? If it's
a smokehouse you want to make sure the smokehouse has been
balanced with good temperature readings in the smokehouse and we
know how long it has to be on at what temperature to achieve a
minimum internal temperature in every sausage that's in that
smokehouse. That, to me, is HACCP. Now you've given me the
background data on setting up a critical control point and your
critical limits. I can go in and look at those records. I develop a
great deal more faith in every pound of sausage that has come out of
that operation than I will if we're just relying on micro testing. Does
that mean we never do micro testing? No. Didn't say that. If a
company so chooses or there is variability in the process then
possibly there should be some verification testing of a
microbiological nature but it depends on how well established the
process is and what sources of variability are. But to set up a
mandatory program for cooked products to say that we have to test, if
the government wishes to do so, fine, but to force companies to do so
I think is not consistent with what we're trying to do. Validated
processes is what we're after and what you have to do to validate
those processes and come up with that kind of warm, fuzzy feeling on all product that comes out of there is what we're after here. Thank you.

MS. FOREMAN: Let me just add that that was not the question that I was suggesting. I was saying if you had a HACCP plan -- Jim's question -- that looked not like other people's and you wanted to persuade FSIS that it should be allowed could you use this to do it? Because in that instance you have some finished product testing that provides an assurance that they didn't get from looking at the plan. I'm looking for more flexibility, not rigidity. Right?

MR. OSER: Some of the intention of Oscar Meyer's doing -- someone said something about pseudo microbiologist. It's kind of what we all are. Sometimes I think microbiology is kind of a pseudo science in some ways. But it's been -- we get into a problem here in verification of systems in some areas, particularly on the fresh side. You can get a lot of information on trends of things by looking at what's going on microbiologically with product. There's a lot of bacterial action there. When you start dealing with pathogens on a finished product just simply testing the finished product and pulling a lot of zeros -- for instance, if you look at salmonella figures from -- that are on --

MS. FOREMAN: Wait a minute, Alan. Are you talking about fresh?

MR. OSER: No. I'm talking about cooked. I'm sorry. If you look at the cooked salmonella figures on fresh products like hot dogs, they're all zeros. I think they've got maybe one in less ten thousand. Does that mean there's no cross contamination going on in the packing industry? Probably not. Because if you look at the figures for
listeria you'll find some. You'll find some. Listeria doesn't necessarily mean cross-contamination. But, if you look at what Oscar Meyer's doing it was found early on when we got into this listeria thing that if you're going to find listeria on the product you're going to find it in the environment much, much, much more frequently than you'll find them on the product. If you take a bad -- what would be considered by industry standards a bad acting plant that would have a five percent rate of listeria contamination that's one sample out of twenty taken on a given day. So you could take nineteen samples, fine enough, and it doesn't really mean anything. I think the average listeria -- I'm pulling figures out of my head -- it's probably closer right now to between one and two percent -- something like that -- so to find out if you really have control of listeria you would have to take ninety eight hot dog samples or a hundred probably and if you found two you know, okay, we're about as good as the current technology. It doesn't really tell you a whole lot. On the other hand, environmental sampling was found very early on that the organism would turn up in an environmental sampling routine much quicker than it would turn up on the product.

So here you have a case where actually testing the product which sounds like it's the best thing to do really isn't the best thing to do because you'll find the problem quicker, which is what we're looking for, by testing the environment. And that's why some of these issues don't have a real clear yes/no answer.

MS. FOREMAN: On listeria.


MS. FOREMAN: But not on salmonella.
MR. OSER: Salmonella is also going to be picked up in the environment long before -- the only way it's on that hot dog is in the environment and the amount of listeria contamination in the environment is far less than there is in listeria so listeria becomes a real nice organism to look for in the environment. Salmonella doesn't survive well in a cold room. It doesn't survive as well as listeria does. And that's probably behind what Oscar Meyer's doing.

There's a difference here between validating or verifying a critical control which is a processing validating step. We don't have to reinvent meat science every time we go through one of those things and validating a whole HACCP plan in a lot of cases microbial validation really makes a lot of sense. In some others it doesn't because you're just going to pull a whole lot of zeros which is going to lead you to believing something that may not be true. A validation of some plans -- maybe a top to bottom review of the plant as opposed to some sort of microbiological limit because your chances of finding a problem are going to be too small microbiologically. It doesn't -- it is a good way to do it but it's not always a good way to do it.

MS. FOREMAN: Thank you.

MR. POCIUS: Joe Pocius with the National Turkey Federation. Just so -- in another life way back when I worked for a company who did canning. In fact, we did re-tort pouches so I want to reiterate what Dane was saying as how you describe the parameters or critical limits for critical control points and, Carol, I think that's what you were asking but you went further and asked, suppose you see a system that you're not familiar with, it doesn't look like anybody else's, how
can you verify that or validate it? In our case, that would be like changing the formula in a pouch. We haven't seen that product before. We have to revalidate. I would expect in the canning industry you do inoculated pack study and once you've done that and once you know if what your time temperature parameters are -- I'm trying not to get into Z and F values here -- but once you know what your time temperature parameters are that's it. As long as you meet those you know you have a kill step. That's the information I would expect for anyone who has a HACCP program that doesn't look very normal. When they describe or they go through a hazard analysis and they say, well, at this point in our process 132 degrees fahrenheit will work well they have to have data to support that. After that, you don't have to take micro samples as long as they meet that time temperature parameter because you know it's a valid kill.

End product testing, as I understand your suggestion on a lot by lot basis, really tells you nothing as Dane said.

MS. FOREMAN: Did I say anything about lot by lot?

MR. POCIUS: You implied.

MS. FOREMAN: No, I don't think so at all. I think that's absolutely contrary to what I suggested.

MR. POCIUS: Okay. If you're talking about doing that as a verification then I'd agree with other people around the table. That's a valid thing to do within a program.

MR. BILLY: I have sixteen names. And if my watch is right we've got about sixteen minutes. I'd like to -- I don't want to rush this discussion. We can continue it if we choose to or keep going after five thirty. But I'd like to encourage people to keep their comments
short, if that's possible, and see how far we can go through this --
through this list.

Next person I have is Marvin.

MR. LEWIS: Lewis. I'm a USDA inspector also. I would like
several gentleman related their credentials. The gentleman from
Hormel, I believe, who has left. I have sixty two years. Twenty years
-- it's farm to table. I was born on a prairie farm in Missouri for the
twenty years; eight years in inspected industry; and thirty four years
as a federal inspector. All as a lowly inspector in charge thirty of
those years. I was involved in the first TQC. In fact, the first TQC
plant in the nation and three of the largest, which two are Oscar
Meyer. One was closed. But, anyway, for ten years as an inspector in
charge. I monitored micro programs, pre-op swabs, operation swabs.
At another company, Eckrich, I believe it was, I did surface counts
and core samples on microbiology. Of course if was quantitative
analysis and not qualitative -- not identifying the particular bacteria
-- but I've been involved with all these programs. We're talking about
TQC basically with the exception of adding of the bac T sampling and
the carcass chilling. I see HACCP as nothing but mandatory TQC. It's
a different critical control points. TQC you had to identify all the
critical control points to comply with the current regulations and we
as inspectors in charge wrote those plans on how to monitor those, do
the verification. I think validation verification is synonymous and
meaning evaluating a lot of paper. But in that time there is
breakdowns in the system. She's right. They might process hot dogs
at a 178 degrees in the third stage of the continuous system. But
once, I believe, there was a breakdown -- a mechanical breakdown.
These things happen. Some fans kicked up. Six minutes or seven minutes of under-processed products. They run twenty hours a day and about six continuous systems. And they were traced, they were found by old fashioned -- -- inspection. Some consumer realized they looked undercooked and watered and they were all recalled. I monitored the recall of the product and then I've got out to anyone but as a mechanical breakdown. These fans didn't kick back on automatically and so they had to be wired. But that just meant we know about the bac T and the finished product testing to get 178 degrees you don't have to worry about salmonella and listeria.

But, anyway, I would like to defend the inspector in charge. All you people from the corporation, from the agency, I'm sure you have a vast lot of experience. They're talking about day one. Mr. Taylor, I think he's been in about a year, maybe three sixty. Me, it's day fourteen thousand something, I believe. And I've been involved with all these programs in the past and nothing is fail safe. I have condemned probably over a million pounds of product after it was past these systems. With all the paper involved, and you can get covered up with paperwork. but I think we reduce it to the single common denominator we're talking about -- inspectors' training. I have inspected 500 companies probably in the thirty four years from Illinois to California. Most as inspector in charge. I've dealt with corporate people at all levels. Five plant managers in the largest plants are also corporate vice presidents and many other big companies and things happen but the inspector is no dummy. I think Dr. Prucha and the other gentleman, Alan, had a problem with the inspectors not wanting a uniformly interpretation but the inspector's
capable of learning such. It's really very simple. You don't have to be a bacteriologist to have a four year degree. I monitored bacteria program. I can observe the manufactured cultures, the swabbing, the incubation and the counting of colonies as well as anyone. And to say we're not capable of science-based and you're going to allow these people in the HACCP program to take three days at a seminar to be a qualified process and authority. Well, I think that we're over qualified if that's what these people need. But I have no problem dealing with any corporate people in my career as well as your illustrious consultants.

MR. BILLY: I'd like to move on.

MR. LEWIS: Okay. I'm done.

MR. BILLY: Thanks. Jim? Jim Hankes?

MR. HANKES: Hi. I'm Jim Hankes. I'm representing the Illinois Association of Meat Processors and I think maybe I may be in the minority today. I'm a small processor. Probably today I had six people working my people or today's production was slaughtering eight beef and then fourteen hogs, some miscellaneous cutting, running our retail store and doing some catering.

There's a lot of us small companies out there. I'm sure as Mr. Billy and staff found out when we got to Kansas City a few months ago and there's a lot of concerns out there. I think one thing maybe the Department really needs to do is to beef up its communication with the small processors. The small processor lack the staffing, the people that have the knowledge about HACCP and HACCP controlled programs. And we rely on the government who is the regulating
agency for this information. To get this information out to all the small plants across the country -- you know -- I know it would be a major undertaking but we're going to get copies of the regulations when they're final and I think a book or some type of handbook with guidelines to start to give a lot of these processors and people an idea of what is coming down the pike is essential. There's a lot of unrest among the small plants out in our state and I know in other states. There's several of them that are looking at different options. Some of the options are dropping inspection completely which I personally feel is a step or maybe ten or twenty steps backwards into the dark ages but these are things people are considering. Other things are going custom exempt and doing away with the inspection that way. There's even been talk about possibility of dropping state programs and going federal where the federal custom exempt is more lax, without regulation. There's talk about going and dropping inspection and going to retail and relying on public health where in some counties, even in the State of Illinois, there's some counties that don't even have public health departments and then there's also talk about, well, I know for a fact that there's people that aren't doing expansion currently, they're not doing any upgrading of their facilities, they're kind of in a holding pattern right now just doing what's minimum, what's required of them till they can wait and see exactly what the mega regs are going to produce. And then I would imagine that once there is a final rule published some of these people would be making decision probably to retire after whatever given length of time they're required to implement the program. I know people are putting the equipment purchases on hold. However, there
is obviously a group of us that are a little more aggressive. We're young enough, we've got kids we want to send to college, we want to keep making a living, we serve our communities, we provide employment to our small towns, and we think that we're a viable part of our communities and for these reasons we want to learn as much as we can about HACCP and fortunately or unfortunately it's my job to go back to our state and our association and get some of this information back to our people and let them know what's going on. There's a lot of people sitting in here from big companies, a lot of inspectors. There's a lot of people here that necessarily don't get in there and probably like myself and get their hands dirty and neither work the kill floor, sausage making, processing, whatever needs to be done. And I think it's important that we look at HACCP. We have implemented several things in our plant which are very beneficial to us and as we learn more about it we're changing our ways and we want to get this information back to the small plants. The small plants are kind of eagerly awaiting to see what's happening. Just in defense of maybe the lack of attendance of this conference from small plants it's difficult to get away. We found out about a week ago when the meetings were going to be held, etc. And for a small plant to take one or two people out of their facility to get away for three days -- four days traveling time -- whatever it takes -- plus the cost of coming out, it's a big job. So hopefully through our associations, through our national associations, state associations, and we can help the Department relay this information back. But I think it is important.

I guess an example I'd like to give real quickly here. There's
even pamphlets and information like this one on E. Coli. And I believe this says up in the corner that it's a USDA -- you know -- Food Safety Inspection Service. I believe the Department put that out. I didn't see this until a couple of months ago. And I didn't get it through meat inspection. I got it through the public health which I sit on our local public health board. And I think a lot of this information needs to get back, filter down to the small plants because we all know the structure of the small plants. It's basically the owner/operator are the main people that operate these plants and oversee all the daily operations and as we read through these and other articles it scares the heck out of us. We have a lot at stake. We're consumers ourselves. We know our customers personally. We have children -- you know -- families, friends, relatives, and we want to do whatever we can to keep our products safe and to even make it safer.

It's interesting whenever a national scare hits the media our business goes up because I think there is a lot of trust in the local corner butcher shop where they know us personally and people do feel better about it and they know what we're feeding our kids they want their kids to eat during times like that and at the same time we're sitting there thinking we want to do everything we can to make sure we do not have one instance of a bad product going out of our plant. And any information that we can get and we look to the Department for education of our employees and our members would be helpful.

MR. BILLY: Thank you. There's a session tomorrow on the role of -- FSIS role of facilitating development of HACCP plans. You're going to hear about some specific concrete plans for providing some of that type of information you're talking about so that will come up
tomorrow so you'll hear more about that. You will be here, right?

MR. HINKES: You bet.

MR. BILLY: All right. Tony?

MR. DUGUAY: Tony Duguay, Quality Supervisor for Jack Pack Foods. We've seen the industry change over a number of years from going from traditional inspection to TQC to PBIS. A lot of the inspection personnel through training have been able to accomplish the trend change and adapt. We've seen some that have not. Under a food science program what is the agency going to do to qualify inspection personnel for HACCP?

MR. SMITH: As I said earlier, we will be doing a comprehensive training program based on this proposal. It would entail at least three weeks of training separate and the design to be delivered to the inspector when they would be using the training so, therefore, there would be a near term training session, a HACCP training session which talks about the principles hazard analysis, those type things, and then a final training package that talks about validation and verification responsibilities. Our whole goal there is equip the inspector to be able to act in the validation and verification enforcement mode so that's how we plan to have our inspectors be able to carry out what we've been talking about here. We're also spending a lot of time developing a supervisor, how the supervisor would act in this arena using statistical process control and things like that to determine whether normal variation is going on and things operating outside variation as far as inspection results and how to coach on verification activities off target and on target. So we plan to spend a lot of time and investment in that -- in that area.
MR. DUGUAY: Thank you.

MR. BILLY: Steve?

MR. COCKERHAM: Thank you. My name is Steve Cockerham. I am a USDA inspector from Grand Allen, Nebraska. I want to state first of all that I think there's a misconception out among industry people. Inspectors -- we inspectors welcome the modernization. Our concern is we don't want the modernization to be on the backs of the public health. We want to insure that public health does not suffer because of modernization.

What I would like to know is -- and I would like to know if under this agency plan what role the slaughter inspector would have in HACCP? Because on the slaughter floor you get a lot of your initial bacterial contamination.

MR. SMITH: We plan, again, the critical control points to control the hazards will be identified and validated in the HACCP plan. Our activity then becomes to verify those critical control points, monitoring activity, and plant verification activity. That would include then what in the slaughter environment when the plant has identified its critical control points and critical points and its activities we would expect inspectors would be trained on how to verify that monitoring and plant verification activity, whether it would be on line or off line, depending on where the critical control points are established.

MR. COCKERHAM: Are we talking about elimination of carcass by carcass inspection?

MR. TAYLOR: No. We have a statutory mandate to do that. It's achieving objectives, some of which may be addressed by HACCP but
others of which are not addressed by HACCP that have to do with wholesomeness and other non-safety defects that we're responsible for addressing. I think the issue we're looking at with respect to carcass by carcass and certainly the top to bottom review has examined -- you know -- various possibilities is not whether we maintain the carcass by carcass but are there ways to improve the use of our resources in carrying that out. Perhaps with HACCP as part of the framework that might permit us to make a better use of our resources so there certainly are issues about how we do carcass by carcass but not whether we do it.

MR. BILLY: Steve? No, Mike.

MR. DONOVAN: Thank you, Tom. Thank you, Tom. Like Carol and Dane and all of those said when I asked for this question that we were on a whole different subject and I think Mr. Taylor answered most of it and I was happy to hear him say that we're trying to enhance our inspection system and use incentives and make the companies accountable with this.

One thing I would like to digress a little bit and say that in the interim we should end up because sanitation is the major building block of good program for anybody and through my twenty eight years and being at just about every inspection job in this agency and this isn't scientific but it comes from being on reviews and also in all of these plants, I would say that I think we have records that show that between five and fifteen percent of the plants out there have an inspection and a plant failure when we look at serious deficiencies and pest control and sanitation. And before we implement HACCP I think we already have the authority to get these plants to a place that
they need to be cleaned up and I think that's one of the interim steps we need to take cause a HACCP program will not work if the sanitation program is not working. Thank you.

MR. BILLY: Ron? Patrick?

MR. BOYLE: Well, when I waived my placard three hours ago I'm sure I was energized and perhaps even incensed about a comment or two that had been made around the table but in the passing time I think whatever it was has been more than adequately addressed.

How fortuitous though that I had hoped to make a general observation towards the end of the session and I didn't realize any of the planned three hours in advance but it's fortunate timing for me. Also fortunate to see the Office of the General Counsel representatives have departed the room. Both during my tenure as administrator of AMS and in dealings with departmental officials since that time it's a rare opportunity to have a conversation without them present.

I have two general observations and one is within the agency's ability to control and the other, while not directly within your ability, I would like to think is within your sphere of influence.

First, in terms of within your ability to control. I know that these hearings were scheduled with short notice and that the agenda was developed over a relatively brief period of time and that some of the commitments that the Department had made in preparation for these meetings would have required certain steps within that brief period of time. The one that I'm specifically referring to is the commitment to prepare in advance the documentation summarizing the issues for discussion today, but more importantly, the agency's
current thinking. And if the lawyers from the General Counsel Office
were here I'm sure they would point out that you have technically
complied with that commitment as of late yesterday afternoon and,
again, for tomorrow's session as of late this afternoon. But I think if
you reflect back on the direction of the discussion that unfolded here
today, at least it was my own observation that as the hours passed
the focus became a little bit more precise. And I also believe that
the discussion became more substantive and I think more beneficial.
I would hope that you found it to be such. And it seems to me that to
the extent the agency is able to get those papers out in a more timely
way to the extent that they can contain as detailed and substantive an
analysis, not only the issues for discussion, but more importantly
your current thinking, I think we would find that every hour from nine
o'clock on is more beneficial and substantive than maybe the first
few hours were here this morning. In that regard I do want to
acknowledge that the Acting Under Secretary did throughout the
discussion interject current thinking on the part of the Department
that I believe was helpful as the discussion went forward but I
believe it would be more helpful if we had that current thinking in
writing in a more timely way.

To the item that is not directly within your control but
hopefully within your sphere of influence. I did have occasion to talk
with the Secretary's counsel, Kim Shnor, who has been with us
through most of the day about this earlier in the day. It was our
expectation, and I believe a reasonable one, that this discussion,
while I think is very substantive and meritorious today, was a
discussion that really was requested by or at least promised by the
Secretary to include him and that was clearly our expectation, not only for today's session but for the other five sessions that are planned, and in his absence, as he told us on a variety of occasions in preparation for these meetings, he would have the Deputy Secretary, Secretary Rominger in attendance, and, indeed, the Secretary did come by later in the day and, indeed, the Secretary was here earlier in the day, but there were seven hours of very good and worthwhile discussion in between and I understand the demands of a schedule, particularly the schedule of a cabinet official. As an administrator I had a busy schedule and I was just an administrator here. So I understand fully the demands and also occasionally the unexpected conflicts that arise. But I would hope that the conflict that arose today was an aberration in the sense that he does fully intend to participate in future sessions or to have the Deputy Secretary present and participating in future sessions because it's out belief that that is truly what is going to result in a more workable and more comprehensive and more effective regulation involving HACCP. So if you could convey that to him and I will attempt to convey that directly to him later today.

MR. TAYLOR: We will work hard to get papers out as soon as possible and I certainly regret the fact that they -- you know -- got faxed out late last night. At least you're able to carry this one away. I think certainly we will do that one in the works for Friday which, again, we'll just get to you as soon as possible. I think with the week interlude we should be better off. We've got drafts of the other ones and we should be better off in terms of getting them out ahead of time and there's some very -- you know -- substantive detailed
issues that we're addressing so I hope that will be helpful to you.

MR. BILLY: Okay. I have eight names. It's quarter to six. They are Irwin, Alan, Bill, Rebecca, Joe, Art Syring, Joe and Bruce.

Alan? Bill?

MR. HARRISON: I'm Mr. Harrison. I forgot what I wanted to talk about. I would like to ask the -- Mr. Taylor a question about the carcasses. Steve asked him a while ago. When you say that you're not trying to do away with carcass by carcass inspection as such are you indicating that the USDA inspector will be doing this inspection or it will be done by someone else?

MR. TAYLOR: We have a statutory mandate for a USDA inspector to examine carcass by carcass, bird by bird and we intend to continue to carry that out. That mandate is not prescriptive with respect to the manner in which we conduct that inspection and we have a certain manner of doing it that has developed over the years as you know and have a lot of experience and expertise about. As I mentioned -- you know -- in response to Steve's question, in the midst of our effort to insure that we are making the best use of the resources we have currently on board to improve food safety we have asked the top to bottom review team that's looking at in-plant inspection roles to consider whether there are alternatives to the current mode of carcass by carcass inspection that would enable the agency to make better use of its current resource and so certainly one question that that group asked and did some analysis and laid out some options and, again, you're probably familiar with them, one possibility that is addressed is the possibility of having some of the tasks currently performed by our inspectors be taken over by plant employees. Not to
totally replace the USDA inspector engaged in carcass by carcass inspection but to delegate, in effect, some of the tasks currently being performed and making the plant responsibility subject to accountability and inspectional oversight by us. So there are host of options and possibilities and so the question we're addressing is are there alternative ways to carry out that mandate so that we would be able to, again, make better use of that inspectional resource. For example, to perform HACCP verification tasks, sampling, microbial sampling tasks, other in-plant inspectional roles as well as roles outside the plant. But the motivation to do that is to make better use of that resource, not to cut that resource. And we've been very explicit publicly, quite frankly, that -- you know -- unless we do insure we're making the best possible use of every inspector we can't achieve our food safety goals as fully as we'd like to and we will have a very difficult time in this budget environment maintaining the resource we have so with those motivations we're looking at how to do it, not whether to do it.

MR. HARRISON: Okay. Would the budget restraints -- could that lead to less than because of budget restraints?

MR. TAYLOR: Less than?

MR. HARRISON: Continuous inspection, bird by bird, carcass by carcass.

MR. TAYLOR: Again, I -- I mean first of all we currently have adequate resource to do that. We're working hard on the current -- you know -- budget process for next year. You know -- we're optimistic about having resource to do that and I don't frankly think that Congress -- just my personal speculation -- Congress is
supportive of us maintaining an adequate -- I hope in the end will be successful in maintaining an adequate resource to do that. That is our absolute commitment in the Department is to pursue and obtain the resources we need to do that job. Congress ultimately makes that decision. But we're in pursuit of the resources we need to do that job.

MR. HARRISON: Thank you.

MR. BILLY: Okay. Rebecca?

MS. HOLLAND: I kind of wanted to leave at five thirty also but due to annual leave and shortage of staff we have to go back home tomorrow and do what we're paid to do. First, I'd like to clarify that in the Jefferson City area of Missouri we do visit each one of our plants daily. Maybe not for very long but we do go in. If there's a problem we insure that it is taken care of in the proper manner. I did get my hands dirty. I started with turkeys and I went -- -- on the kill floor. So just to go on a little bit farther, I think that the end result all of us will want is to assure that the consumer does get an unadulterated wholesome product. I have enjoyed listening to each and every one of you today and we try to have good rapport with our - - with the industry in each one of our duty stations.

There's -- I'm taking notes here. Cutting it down. Okay. There's been a lot of referral as this -- the inspection, industry, HACCP, being referred to as highway -- automobiles -- and the patrol officers have advanced technology. They have radar, laser, which caught me, even -- you know -- photography. There are lawbreakers but that doesn't necessarily make them bad people. They're only human beings. And no matter how many facets of checking if there's no enforcers the technology alone will not work. We've got to blend
the two of them together. HACCP does have to enhance what we have. And I think if you work the two of them together and because we feel that industry maybe needs to be patrolled -- you know -- that doesn't make you bad people either.

In closing, the main objective that we all -- you know -- all of us must attain is -- okay -- last week I took my daughter and her three children out for lunch. Of course, the kids want a hamburger, french fries and a soda which ended up being a happy meal. My three year old grandson, Michael, took his hamburger out of the box and he said, see if it's okay, mommy. And that's what we've got to do. We've got to make sure that that hamburger is okay for those little ones to eat. And thanks for your time today.

MR. BILLY: Joe?

MR. MAAS: I'll keep it brief. I'm a small processor. Back when you said that somewhere along the lines someone along with my colleague from -- I guess from Illinois down there -- my name is Joe Maas. I own a meat processing plant in Cincinnati -- JTM Provisions. I just wanted to say a couple of things real quick. I wanted to point out the one thing, at least in my case and in companies my size, my salary is paid by the consumer. There's just no way out of that. I do not get any income from anyone but the consumer. On occasion I hear people say -- you know -- that hey, we got to take responsibility for the safety of the products and not let it be the role of the USDA's. Well, I can tell you in my plant I carry -- I carry the responsibility for every pound of product that leaves that plant. The USDA carries none of the responsibility. If someone were to be harmed by something that I sell it's not the USDA's problem. It's just flat plain
mine. I would certainly lose everything I worked for my entire life. I would leave it go at that but if HACCP is something that is going to be decided that is something that I have to do then I'll do it but I'm perfectly comfortable with the system that I have in place in my plant. I personally, myself, walk the floor every day. I own the company with my three brothers. One of the three of us are there every day walking the floor, making sure everything's going okay. I don't envision myself ever sitting in an office having somebody feed me reports that I'll go over to make sure everything's going okay. I guess I'll produce these reports for the USDA inspector. I, myself, will go out and inspect the plant myself and make sure that everything's going okay. Thanks for your time.

MR. BILLY: Art?

MR. SYRING: Art Syring from Missouri. I have two questions. One of them about the -- -- when E. Coli broke out. You made a statement that you were going to hire 200 inspectors to get this thing under control and as of this day I think we only have fifty. What happened to those other hundred and fifty when money was allotted for them to get hired?

MR. TAYLOR: I mean that issue predated me somewhat and I frankly -- I mean there was a budget issue essentially and --

MR. SYRING: Well, you said as the weather changes you'd hire them.

MR. TAYLOR: I mean to be absolutely literally precise I did not send you a letter cause I wasn't here at the time. I mean -- so I can't -- I'm just not conversant enough with the facts of that particular exchange to -- -- as I'd like. I don't know -- Bill, can you shed --
MR. SMITH: Let me check.

MR. TAYLOR: We'll check and give you a -- you know -- give you a -- we'll lay out the facts. We'll do that tomorrow if you're still here or privately otherwise.

MR. SYRING: All right. One other question was brought up. In a poultry slaughter plant they have several thousand reprocessed birds in a day's time. On our microbial testing they're not included in the microbial testing. Why? They're contaminated birds sent back to reprocessing area to be washed out. When you do your test you test the line but the reprocessed bird, it goes back to the chiller and not part of those sample selection.

MR. SMITH: I'm not sure on what micro testing you're talking about. The -- what the reprocessing would be a critical control point probably it would need to be controlled because they have a definite hazard there and whatever the plant uses to monitor that activity and verify that activity is what we'd be using. I'm not sure what micro testing you're talking about though on the line as opposed to reprocessing.

MR. SYRING: That's your HACCP baseline testing for salmonella contaminated birds. When you all are going to do these tests on the line to verify the contamination of the birds the reprocessed birds is not included.

MR. BILLY: We'd like to get back into that. I think you're talking about baseline --

MR. SYRING: Baseline is what I'm talking about.

MR. BILLY: What we'd like to do is get with you separately and answer your question so I can wrap this up. I'm not diminishing the
importance but --

MR. SMITH: The birds are sampled out of the chiller. Am I correct?

MR. SYRING: Correct.

MR. SMITH: And, therefore, reprocessed birds go into the chiller so they have -- and it's a random sampling so there's nothing to say the reprocessed birds are not being sampled.

MR. SYRING: They're not selected.

MR. SMITH: I don't know how we can determine -- I mean if they're all going into the chiller and they're being pulled coming out of the chiller how do we know --

MR. SYRING: I'm going to let a slaughter inspector explain it to you.

MR. CLOSE: I'm Rick Close. Our instructions when we were pulling these samples were to make sure we did not pull a reprocessed bird. We pulled one hundred percent, untrimmed birds for our baseline sample. And that was our instructions -- do not pull a reprocessed bird for this sample.

MS. HOLLINGSWORTH: This is Jill Hollingsworth. I believe that the reason for that there was a basis for that and I believe that one of the things that was discussed when we were taking these samples was that if we pulled the reprocessed birds and used them as part of the baseline what you would have represented by the reprocessed birds are those birds that were intentionally treated with an anti-microbial because they are required to be washed with high chlorinated water and it was felt that they would skew the national averages to what is the average salmonella because they were
selectively treated with chlorine.

MR. CLOSE: All the poultry equipment's got chlorinated water on it. All them birds is subject to chlorinated water going down the line.

MS. HOLLINGSWORTH: The equipment does but not necessarily the wash water.

MR. CLOSE: Okay. Is it a true baseline test though when we exclude those birds?

MS. HOLLINGSWORTH: I think it's true baseline for what is on the line. There have been separate studies done of just the reprocessed birds as a separate population but it was felt that they were such different populations that to mix them didn't give you a picture of nationwide.

MR. CLOSE: Okay. So the birds that we do know were physically fecally contaminated we're not doing no tests on those birds at all. We're going to let those birds go.

MS. HOLLINGSWORTH: There have been baselines done on just those birds as a separate project.

MR. CLOSE: Not in our plant.

MS. HOLLINGSWORTH: It has been done. We can provide you those studies. There's been three or four of them where just the reprocessed birds were sampled and analyzed but they don't normally represent the average carcass on the line because they've been naturally specially treated with anti-microbials.

MR. SYRING: What was the baseline on the two?

MR. BILLY: I'm going to -- again, I appreciate this but in fairness to everyone what I'd like to do is suggest that you folks get
together separately and share the data and the information and anyone
that's interested you're welcome to participate in that. There's one
more speaker. Bruce? Thanks for being patient.

MR. TOMPKIN: Everybody in the room's been patient. My name is
Bruce Tompkin. I'm from Swift Eckrich. I'm not a pseudo
microbiologist. I happen to be one. And I really wanted to respond to
Carol Tucker Foreman's question some time ago relative to whether
you could have two HACCP plans wherein one end product testing may
be appropriate and another not.

MS. FOREMAN: With all due respect, that wasn't my question so
that may be your statement but that was not my question.

MR. TOMPKIN: Then I'll withhold my statement.

MR. BILLY: That's my entire list. I'd like to thank everyone. I
repeat again that we out on the table for those that haven't received
it the background paper and the current thinking paper. They're
available. I encourage you to look at them. We'll start promptly at
nine o'clock tomorrow morning in the same room. Thank you very
much.

(Whereupon, at 6:00 p.m., the meeting was recessed.)