

P R O C E E D I N G S

1
2 MR. BILLY: It was just suggested that I announce the
3 availability of an overflow room. It's on this end of the building. It's
4 4347. There's a TV monitor in there where you'll be able to watch and
5 hear the proceedings. I think for any people attending, particularly
6 employees of the agency or the Department, that don't expect to be
7 speaking I would encourage you to consider moving to the overflow
8 room. Again, it's 4347. You go out the door here to my left and
9 there's an L, turn left again, there's an elevator and it's a couple of
10 corridors over so we want to make sure that everyone that wants to
11 contribute and actively participate in the dialogue does have a chance
12 to do so. So thank you very much.

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

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

24 MR. GLICKMAN: Thanks Tom. Good morning everybody. You'll
25 notice we changed the seating format a little bit so we could be
26 closer to each other. I don't know if that's good or not but probably
27 breaks the ice a bit.

1 First of all, I'm pleased that such a wide spectrum of interests
2 are here for the first of six issue focus meetings on the HACCP
3 proposal. An important task lies ahead of us -- the mutual goal of
4 improving food safety and updating the meat and poultry inspection
5 system. It's essential that each of us keep this important goal in
6 mind as we work over the next several weeks.

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

22 MR. BILLY: Thank you very much. I'm going to make a few
23 announcements -- some of the logistics -- give you a sense of the
24 schedule for the day and then turn to specifically to the agenda. I
25 indicated earlier, and I want to repeat again, that we do have an
26 overflow room. It's room 4347. It's in this building. You go out the
27 doors here to the left and up the elevators to the third floor and it's a

1 corridor over. There's a monitor in there where you can watch and
2 listen to all the proceedings and I would particularly encourage
3 people that don't plan to speak to consider moving to the overflow
4 room so to make sure we have space for those that want to actively
5 participate.

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

21 In terms of the schedule for today what we propose to do is to
22 have this opening session run from nine till ten thirty. We'll have an
23 half an hour break from ten thirty to eleven, then another session
24 from eleven to twelve thirty. We'll break for an hour and a half --
25 from twelve thirty to two and then we'll have another session from
26 two to three thirty, a half hour break from three thirty to four, and
27 then a final session from four to five thirty. I'm going to work real

1 hard to get us through today's agenda within that time frame. If it's
2 necessary and it looks like it's important to keep going we're going to
3 be flexible in terms of keeping the discussion going to try to bring it
4 to closure because there's a lot of important issues scheduled for
5 each of the days and if there's a new issue that comes up that's not on
6 the agenda that there's a sense that it's important that we have a
7 discussion about it we do have some time on the last day -- on the
8 29th -- where we can put it into that time slot and discuss it at that
9 time.

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

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

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

27 MR. TAYLOR: Thank you, Tom. Let me first just join the

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

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

1 the principles and I just want to walk through briefly the goals and
2 principles.

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

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

21 First principle is that we believe we need to adopt and
22 incorporate into the system modern science-based process control
23 techniques to target and to work to prevent significant food safety
24 hazards. That's a way of saying we need something like HACCP as the
25 operating frame work for food safety in meat and poultry plants. The
26 targeting of harmful bacteria to achieve food safety goal is also a
27 given within the concept of a HACCP system. HACCP is designed

1 process control. Preventive process control is designed to target and
2 reduce the significant hazards. So the first principle is simply
3 modern science-based and preventive process control needs to be the
4 operating frame work.

5 Second, we believe that our system needs to more clearly define
6 both industry and FSIS responsibilities and accountability for food
7 safety and there are many aspects of the current system that we
8 think blur the delineation of responsibility as between industry and
9 the agency and its inspectors. We have a system today that is based
10 on command and control regulation and fairly detailed prescription of
11 much of what plants do in their daily operations to produce foods that
12 meets our regulatory requirements. On the other hand, in certain
13 critical areas we lack clear performance standards -- clear measures
14 of what the acceptable outcome is of the efforts that plants are
15 making to produce safe food and this is especially true, again, with
16 respect to harmful bacteria on raw products. So we need to more
17 clearly define industry and FSIS responsibilities and accountability
18 for food safety. Again, the HACCP proposal, the HACCP concept itself
19 was intended to address this because HACCP is, of course, a frame
20 work within which very clear the plants take responsibility for
21 designing process controls adequate to meet appropriate food safety
22 objectives. The sanitation SOP element of the proposal also was part
23 of this process of delineating what the roles and responsibilities are
24 of plants and inspectors when it comes to insuring adequate
25 sanitation in plants. We've got to shift, as a general proposition, as
26 much as possible, we believe, from the command and control approach
27 to regulation to an approach that's based on performance standards

1 because we believe performance standards are a powerful way to
2 clearly articulate what industry's responsibility is ultimately and
3 provides an objective tool for government oversight to use to hold the
4 industry accountable for meeting clearly defined objectives. In
5 particular, we believe that we need some tool. We think it is
6 essential that the system incorporate some meaningful and practical
7 measure of accountability for controlling and reducing harmful
8 bacteria on raw product. While this was the goal of the interim
9 targets for pathogen reduction in the proposal, we got many
10 comments on this aspect of the proposal, of course. Very few
11 challenged the goal of controlling and reducing harmful bacteria. We
12 got comments from many different perspectives on the approach that
13 we took to achieving that goal and we have a whole day set aside on
14 Friday to discuss that issue. But the objective of having a practical,
15 meaningful measure of accountability for controlling and reducing
16 harmful bacteria is very central to our initiative.

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

26 The third principle that we looked to incorporate in our system
27 is to provide greater flexibility, greater incentives for meat and

1 poultry plants for the industry to innovate to improve food safety.
2 We believe that technology innovation, innovation in process control
3 is part of the solution to meeting our food safety goal and reducing
4 food-born illness. We think that the shift from command and control
5 to performance standards is the essential tool for providing the
6 greater flexibility and greater incentives to innovate while, again,
7 maintaining and again enhancing the role that the government
8 inspector can play in insuring accountability. But providing greater
9 flexibility and incentives to industry to innovate to improve food
10 safety is a very important part of our initiative.

11 Fourth, we have said and we believe strongly that we must
12 address food safety from farm to table. The proposals we're
13 discussing today, of course, focus on the in-plant environment but we
14 all know that hazards as well as opportunities to reduce hazards
15 arise at every step of the food production and marketing continuum
16 from farm to table, including with respect to how products are
17 handled at the ultimate point of preparation and consumption and we
18 do need to have a system and a strategy that addresses food safety at
19 each step along the way. The February proposal included in the
20 preamble discussion at a conceptual level of our strategies in these
21 various other areas outside the plant, we've got a number of
22 activities going on to compliment the rule making which, again,
23 focuses on the in-plant environment. It's an area that we can perhaps
24 have some conceptual discussion of. I think the last day has time
25 provided for this. But it is very clear that we will not achieve our
26 food safety goal ultimately unless our system addresses food safety
27 from farm to table.

1 And, finally, it is absolutely essential to the success of our
2 food safety initiative that we make better use of both public and
3 private resources to improve food safety. The resources are finite
4 for everyone, whether in government or in industry. It is really
5 critical that we all focus our resources on the task that will
6 contribute the most to improving food safety. The agency believes
7 that the HACCP frame work is a tool for all of us to better focus our
8 energies on the critical points in the production process that affect
9 food safety but for our agency the effort to focus resources really
10 goes very far beyond the rule making itself. We have to
11 fundamentally transform the way which we use our resources day to
12 day to oversee the activities of industry. The regulatory reform rule
13 making package will begin that process, begin to remove some of the
14 activities, both in-plant and headquarters, that we believe do not
15 contribute sufficiently to food safety. But we also are going through
16 a fundamental re-examination of the institution itself and this is the
17 top to bottom review process that many of you are very familiar with.
18 We are in the midst of a process of looking critically at how our
19 agency defines its regulatory roles in a new HACCP-based food safety
20 environment, how we allocate our resources among safety activities
21 as compared to issues involving economic adulteration, as between
22 in-plant activities and activities outside the plant between
23 headquarters and the field. It's time to fundamentally reassess how
24 we allocate our resources. And it's also critical that we look at our
25 organizational structure. HACCP is going to require an approach to
26 decision making in the field as well as in headquarters that is
27 different and necessarily, I believe, will need to be more expeditious

1 than decision making is in the current system. That alone requires, I
2 think, important organizational change so that the system will
3 function better. But there are also opportunities to streamline our
4 overhead and management functions and structures to make better
5 use of our resources to apply more of our resources on the front line
6 of food safety functions than we do today. I think in the Federal
7 Register of Monday or Tuesday of this week we published a notice in
8 the Federal Register announcing the availability of preliminary
9 reports produced by ten teams of FSIS employees addressing various
10 topics within the top to bottom review. This effort that these
11 employees invested in developing those reports resulted in some six
12 hundred pages of very substantive analysis, background discussion of
13 current programs and options for meeting the objectives that I've
14 outlined for the top to bottom review. So in case there are those of
15 you who don't feel sufficiently engaged by participating with us in
16 the rule making effort we have six hundred pages of top to bottom
17 review material that we have solicited your comments on by the end
18 of October. And as we say in the notice, on specific topics being
19 addressed in the top to bottom review, as they become ripe for
20 further public dialogue we will certainly be having further
21 opportunities beyond any written comments you may choose to
22 submit. There will be further opportunities for dialogue on the top to
23 bottom review issues.

24 As I said at the outset, the comments generally support the sort
25 of principles that I talked about and I find that enormously important
26 because it says that we're all working towards the same general goal.
27 We are operating to a larger extent. I'm not saying there's unanimity

1 here but there's a rather broad area of agreement about some of the
2 general principles that need to be built into the system. What we've
3 got before us is a very large number of difficult questions about how
4 to get there and the comments did raise a number of very, I think,
5 cogent criticisms of our proposals as well as suggestions for how to
6 improve our proposals. There are a large number of issues that we
7 are going to have to resolve in order to get the fund rules that will
8 meet our objectives. I think we have an agenda that is well organized
9 around the principal topics -- key issues that were raised in the
10 comments in how we're going to get there, what's this new system
11 going to look like in reality and practice, and then what's the role,
12 what's the rationale, and how should we deal with the substance of
13 some of the so-called near term interventions that we proposed --
14 the sanitation SOP's and microbial treatments and carcass cooling
15 standards. So we clearly have our work cut out for us over the next
16 several days and coming weeks and months but we are enormously
17 optimistic about our ability to make good decisions and arrive at a
18 final set of rules that will achieve principles and goals, again, I think
19 very many of us agree on.

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

26 MR. BILLY: Okay. I'd like to now before we open it up
27 specifically to the initial items on the agenda as well as any

1 observations or discussion on Mike's comments, I'd like to review the
2 ground rules that we published in the Federal Register. I think these
3 ground rules are important to all of us and I'm going to work very hard
4 to make them work for us.

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

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

21 I encourage people not to make repetitious statements. If you
22 make a point let's provide time for others to react and provide their
23 point of view as well. It's clear from the comments that we've
24 received and the scoping sessions that a number of interests have
25 been raised with regard to legislative changes. If discussions -- if
26 people bring up points that relate to a need to change legislation I'm
27 going to request that that be deferred. The Secretary is planning a

1 food safety forum in October and there will be ample opportunity for
2 everyone to present their views in terms of legislative changes of the
3 opportunity to talk about how legislative change might facilitate
4 what people are trying to do in terms of the current system as well
5 as how this system might be improved.

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

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

26 Okay. Given that, what I'd like to do is to open the discussion. I
27 want to refer you to the agenda. Look at September 13th schedule.

1 The things that Mike talked about in terms of the general philosophy
2 are open for discussion but I'd like to approach it in the context of the
3 agenda and focus initially on the first item -- Item A -- the near
4 term measures. Now this is a discussion about the role and rationale
5 of having near term measures, not the specific -- well, we don't
6 agree with the temperature you propose for -- we're going to have
7 that discussion at a later time. This is a discussion, hopefully, about
8 the idea of having near term measures while HACCP is implemented
9 over a several year time period. So with that I open the floor and
10 encourage comment on that question and on that issue.

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

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

1 safety officer of the company.

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

11 What I'd like to do this morning, since we didn't have others that
12 were volunteering, is talk with you a little about HACCP and share
13 some of our views on this important subject. I don't know how
14 familiar you are and whether you've ever been able to really use the
15 process but I think we're impressed with it. At the outset I'd like to
16 insure you that we have implemented HACCP. We are using HACCP at
17 Hormel Foods and we have for a number of years. We are pleased the
18 Department has published. We have worked with AMI to petition for
19 HACCP, to use those principles in our business. We need that. It's
20 important that we have a cooperative approach to implementing
21 HACCP across the industry. It's just not going to work if we're not
22 working together to further develop what's already in place in terms
23 of food processing and what we're doing with HACCP. We worked very
24 hard, as Michael pointed out, to build prevention in our processes. We
25 do that wherever we can at Hormel as do other processors and I think
26 if there's one thing we've learned over the years is that we do not
27 test these problems out of our products. We prevent. We build

1 prevention into them. We might use a thermal process, we might use
2 a PH control, some kind of a hurdle in many cases as part of the
3 process so that we have that prevention mode in place. We also put
4 our name on each one of these products and we are responsible for
5 those products in the marketplace and we take that responsibility
6 very seriously.

7 I'd like to just for a minute give you an example -- a working
8 example or two of HACCP -- how it might seem like a relatively new
9 term but I think Pillsbury in the 1960's coined it. Maybe Howard
10 Baum in there was responsible for coining the term HACCP. We've
11 used in the acid canned foods producing Hormel chili and Spam for
12 over fifty years. We like the discipline that we've incorporated in
13 there that has developed through the trade association. In the early
14 days going back in the 20's and 30's there were significant problems
15 with clostrating -- -- and an understanding how to control that
16 organism and other pathogens. When you control that one fortunately
17 you take the others out. Those GMP's were developed through the
18 National Cannery Association better known today as the National Food
19 Processors Association and those were shared with FDA and in the
20 70's those GMP's for low acid canned foods were formalized and in the
21 mid 80's USDA formalized those same guidelines. I think they have
22 served not only the industry but consumers and others as probably the
23 leading working example of how HACCP will effectively operate in
24 the food chain -- how it can work there. There are other examples
25 that I could use this morning and I can get into the detail if we'd like
26 to do that but we can talk about roast beef and how we use HACCP to
27 produce that kind of a product; cooked patties; we can talk about dry

1 sausage and we can get into any one of those, but I don't want to use
2 more than my share of the time here. I just have a very firm
3 conviction that prevention is the mode that we need to be in and when
4 I say that, in fact, we put our name on these products, they're before
5 the consumer. If Washington thinks it has a contract with America
6 we have a contract with individual consumers out there. And if we
7 tarnish that more than once or twice and there will be errors. I don't
8 care how well we adapt HACCP and develop and science is always
9 developing there will be some areas. But if we tarnish that name out
10 there we're no longer in business. And that's the motivation that
11 drives our conviction behind HACCP and how it works and where we
12 ought to really be. I would agree. There are some areas where we
13 need to all improve and we'll do that but we do that when we have the
14 interest of the consumer at heart. You know, that contract or that
15 consumer, we can't violate that and we'll move those processes
16 forward and I know that we're not at the end of all of the
17 interventions that we're eventually going to find to use with these
18 products. But we've got to have the flexibility, and as you mentioned
19 Michael, it's part of the plan to let innovation work some more here.
20 Frankly, we've all been pretty constrained and we'll bring some more
21 of those interventions to the front that will help us and we'll build
22 HACCP plans around those. We'll put the stop signs in there and when
23 a process is not functioning properly make those -- when a process
24 deviation occurs we'll correct that.

25 So with that I would just leave you with those thoughts that we
26 apply what we're doing. I know you asked that the near term
27 interventions be the initial focus here and I've intentionally done

1 what I've just done and I think those near term -- that focus is part
2 of HACCP. We're going to be doing all of those things when we have
3 HACCP in place and whether -- and it's hard to decide where you need
4 to be with all of those details and I don't mean to slight details but
5 frankly that's what they are in the scope of the big picture of putting
6 those interventions or having those processes in place to insure safe
7 foods. Thank you.

8 MR. BILLY: Thank you. Lee.

9 MR. JAN: I'm Lee Jan. I'm the Director of the Texas Meat Poultry
10 Inspection Program. I'm here as a representative of NASDA and the
11 National Association of State Meat and Poultry Inspection Directors.
12 I would like to address some of the near term measures just real
13 briefly -- maybe some philosophy -- but we totally agree that HACCP
14 is the way to go and there has to be a transition period and I think the
15 near term measures are a way or a step to get there. I do believe,
16 however, that there are some -- you're kind of reluctant to give up
17 the command and control and I think that in the near term FSIS does
18 need to start giving up the command and control and what I'm talking
19 about is the mandatory requirement for carcass washing. I think that
20 rather than mandating carcass washing that should be authorized or
21 allowed to be a process that the plant chooses to improve but don't
22 add more command and control. There are probably several or many
23 processes that without carcass washing are doing a great job in
24 meeting the goals. We just don't have the data to maybe to back that
25 up at this time. And speaking of the data, the testing is another near
26 term issue that tends to be in command and control and I think when
27 we think about if it wants to be a commanded requirement then that

1 commanded requirement should be at the cost of FSIS. When you
2 allow it to be optional or to be a process -- a part of the process as
3 we expect with HACCP in the future, then those tests that would be
4 required to verify that that's working should be a part of the plant's
5 responsibility. But to make a command decision that every species
6 every day, regardless of volume, is going to be tested and we're going to
7 make the plant pay for it, we're saying -- we're giving you
8 responsibility but we're telling you how to do your responsibility and,
9 although we need to have guidelines, if FSIS is going to make those
10 demands then they should pay for them and if we allow or move to
11 voluntary testing to verify their own processes that should be paid
12 for by the plant as part of their process and verification as has it's
13 always been. Currently we test for economic -- you know -- percent
14 fat, water, or whatever. FSIS pays for that and we go to the more
15 expensive testing where we're looking at maybe putting some people
16 out of business if you say you have to test every cow that you kill. If
17 you're a small business -- you know -- that's just going to be cost
18 prohibitive. So as long as the process or the plant's process can't
19 dictate the time for the testing or the frequency of testing then I
20 think that should be, again, paid for by the FSIS.

21 Now, standard operating procedures, that to me is a great move
22 toward relinquishing some command and control. Now you're telling
23 the plants -- you know -- you have to take control, you write up what
24 you're going to do and we're going to look at that. That's the way we
25 need to be going. Let's go with standard operating procedures written
26 by the plant with some input from FSIS or from inspection programs
27 because of the expertise and the background and can see where it's

1 going but let the plants put it in motion and then let FSIS or state
2 inspection programs verify it's working. But I think that's what we
3 need to be sure that these near term objectives do start relieving
4 command and control in those places that it can't be and it still has
5 to be felt that it's directed then if you're going to direct it, make it
6 mandatory, then pay for it. Thank you.

7 MR. BILLY: Judy.

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

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

24 Who's next? Rosemary?

25 MS. MACKLOW: I'm Rosemary Macklow, Executive Director of the
26 Meat Association. The issue here today is not whether HACCP is the
27 goal for the future. It is rather how do we retool today's meat and

1 poultry industry away from the expectations of the traditional
2 procedures and towards accepting HACCP responsibilities and what is
3 the role of government in that process and there are several things
4 that we have to address if we're going to make this transformation
5 efficiently and effectively to meet our common objectives. That's
6 what we're here to talk about.

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

27 In the new roles we are concerned that there is set forth in the

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

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

25 We've heard some rumors about day one. We've read some things
26 in the trade press about how things will be but we still don't have an
27 understanding particularly at the plant level and it's terrifying to

1 small plants if they've always approved by blueprints for ninety years
2 and now tomorrow they're not going to do that anymore. What
3 authority does this give the local inspector in the plant? Can he come
4 in because he doesn't like the drain or something or other and he can
5 stop that operation? These are very every day working relationships
6 and that's just one of many, many of them. How are you going to
7 convert that field force? I don't want to be repetitive because you're
8 rule me out of order.

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

19 The 1906 social reforms of Upton Sinclair inspired that first
20 mandatory meat inspection law. The '67 amendments were dubbed the
21 wholesome meat act and they respond by the unlawful entry of horse
22 meat into the school lunch programs. We're not here today, as you
23 properly said, to design changes in the statutory authorities but we
24 are doing something that may be a precursory to that and I noticed Dr.
25 Goldberg not far behind me listening carefully. We are looking at
26 issues that were energized by a very serious illness and death to our
27 nation's most precious resource and that was children who ate

1 improperly prepared hamburgers. We, as an industry, want to do it
2 right. We want, as Secretary Glickman's mother admonished him, to
3 make food safe. We are but one segment in that long food chain from
4 the farm to the table. We want to do everything reasonably possible
5 while the food is under our control to make it safe. That's why we're
6 here today. That's why I came back from New Zealand and I'm not
7 quite sure what day it is. That's why we need to hear from the
8 Department how its plans to carry out its part in this effort. It has
9 kept me awake at nights -- not really, but almost -- worrying about
10 that issue because I know the day to day stuff that is going to go on
11 in plants and a lot of people around this table are equally concerned.

12 Thank you, Tom.

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

23 Caroline?

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

26 In 1985, the National Academy of Sciences Report was issued
27 that first called upon the implementation of HACCP for meat and

1 poultry products. Since that time we've had ten years of outbreaks
2 and of illnesses. We don't know to what extent HACCP will prevent
3 those but we all have a lot of hope that once it is implemented we
4 will see a major reduction in food-born illness and outbreaks.

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

14 MR. BILLY: Barry.

15 MR. MARSHALL: Yes, Mr. Chairman. Thank you for this
16 opportunity to attend this very informative conference and I think the
17 outcome's going to be extremely good. I'd like to say that I am from a
18 country, New Zealand, which, of course, is one of the major exporting
19 countries in the world for sheep and beef and we export eighty to
20 eighty five percent of everything we produce. I won't tell you the
21 jokes about the number of sheep as per population. However, we're
22 very supportive of the measures being taken by FSIS to improve food
23 safety. We know, as an exporting country, how important it is to
24 make sure that your product is acceptable. In this respect, there are
25 a number of issues here that certainly fit in with New Zealand's
26 concepts, although we may defer somewhat on how it's actually
27 achieved. We agree in the principles, the end results, and we have put

1 forward a fairly substantive submission suggesting that in the New
2 Zealand situation, which is totally different than we do things here,
3 that we can actually achieve the same end result as what is trying to
4 be achieved here.

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

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

1 maintained clean throughout the processing, unless your employees
2 know what they're doing and know what is right and what is wrong
3 then it's going to be an uphill battle so I think that those are issues
4 that industry can be addressing right this moment without any input
5 at all from government.

6 In terms of carcass chilling and freezing requirements it's quite
7 a standard to me that this country really has only on the books one
8 chilling requirement or one requirement as far as temperature and
9 that is actually the temperature at the cutting room facilities. Now,
10 New Zealand's found -- well, simply because we're transporting meat
11 so fast -- that really you need the chilling regime to occur so that
12 the carcass temperature decreases the moment the hide comes off
13 and viscera comes out so you've actually got a decreasing
14 temperature curve and that's necessary to reduce this level to a level
15 where the bacteria don't multiply. So we are very supportive of what
16 is being proposed in this initiative about temperature reduction.
17 We're totally opposed to the parameters that are actually being
18 described. That's an issue we'll take up later on. We consider that
19 seven degree celsius which is forty five degrees fahrenheit is against
20 4.4 celsius which is forty degrees fahrenheit is much more practical,
21 cost effective, and everything else, but that's another issue.

22 In terms of -- well, generally, I'd just like to finish at this
23 point of saying that New Zealand's very supportive of what's been
24 done. We feel that the principles of HACCP need to be applied but
25 many instances we're actually talking about good manufacturing
26 practice. We, in New Zealand, are not going to mandate the use of
27 HACCP but it's quite interesting just by virtue -- well, we're not

1 going to mandate them simply because we actually have mandatory
2 requirements for certain things in the system anyhow and when you
3 actually collectively bring them together perhaps that's somewhat
4 similar. However, the idea of good manufacturing procedures,
5 industry responsibility for controlling these, and the import by the
6 controlling authority to monitor it I think is the most effective way
7 of going. Thank you.

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

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

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

27 However, with the HACCP approach we're able to embrace our

1 uniqueness and focus our resources on the process rather than on the
2 regulation. We feel a focus of resources by the industries and the
3 agencies on the implementation of HACCP systems from farm to table
4 will be more effective in reaching both our shared goal in producing a
5 safe and safe meat and poultry supply to consumers.

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

25 In developing our HACCP plans we have taken this into
26 consideration when doing a hazard analysis. In addition, the hazards
27 and the point at which those hazards enter into our process are much

1 different than those from typical hog kill operations. Therefore, we
2 feel mandatory critical control points should be avoided to allow
3 processors the flexibility and in the end the agency to create
4 programs that are more specific to individualized processes.

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

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

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

1 can. Thank you, Mr. Chairman.

2 MR. BILLY: Larry.

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

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

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

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

21 Just a few experiences that I've been asked to relay. Recently, I
22 was in a plant and I saw in the staging area a product that looked
23 suspect ready to be included in product. I tagged it. It was sampled
24 and it was found to have a six percent insect infestation. Had I not
25 been there that product would have been included and been out on the
26 street. Within the same couple of weeks over a thousand pounds of
27 ground beef that I found to be suspect that was in the staging area

1 ready to be included in product was found to be by laboratory analysis
2 with a bacteria count such that it was determined that it was in fact
3 off condition.

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

6 MR. BILLY: Tom.

7 MR. DEVINE: Thanks. I'm Tom Devine with the Government
8 Accountability Project. My comment is also triggered by Ms.
9 Macklow's remarks. Her question was on the role of the inspectors
10 and I think it's fairly common sense that what the role of the
11 inspectors has to be. It's to keep the HACCP system honest.
12 Somebody's got to do it and that's the role of the inspectors. Whether
13 or not we're layering efforts at honesty depends a lot on questions I
14 would have and I'm looking forward to hearing answers to from the
15 industry representatives here about what they are planning on doing
16 to keep the HACCP systems credible and reliable. If the organization
17 were to work our primary philosophy is that sunlight is the best
18 disinfectant. But the meat industry is particularly dark in terms of
19 public oversight. This is an industry which will not let the public go
20 in its plants, will not let the public see public health records, will
21 not let workers have job rights against being fired for raising public
22 health concerns. At the previous HACCP round table I'm strenuously
23 opposed having any type of internal corporate structural autonomy for
24 the enforcement personnel who will be responsible to keep those
25 HACCP plants credible in practice as well as on paper. It's very
26 difficult to have very much confidence in industry without federal
27 inspectors keeping it honest under these circumstances. If we've got

1 layering it's a paper thin layer versus a thick blanket and I want that
2 blanket to keep me warm quite frankly. But I know that all of us are
3 coming to these meetings very open minded. We have a lot to learn
4 and what I'm looking forward to learning over the next few weeks is
5 the industry's plans to keep their HACCP programs honest and credible
6 even for the weakest links in the industry, those few plants who are
7 willing to make money off of unsafe meat and poultry. The details of
8 the industry plans from their international HACCP associations and
9 conferences and meetings will be very educational for us in depending
10 how much responsibility the industry's willing to assume. That
11 creates a direct link to how much we have to rely on the federal
12 government.

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

24 MR. BILLY: Mike Taylor.

25 MR. TAYLOR: Lest we duplicate the May hearing and the agency
26 sits passively by while the conversation goes on I just want to make
27 an observation or two about what I've heard hopefully for the purpose

1 of fostering some dialogue and inviting -- you know -- inviting
2 further comment, criticism, suggestions.

3 On the issue of inspection, as Tom said, the agenda provides for
4 some really detailed focused discussion later today and my guess is,
5 tomorrow as well, on the issue of how the agency, in its current state
6 of thinking, envisions inspecting HACCP. The one observation I
7 wanted to make is that I think it was clearly laid out in the preamble
8 to the proposal and it's certainly something that I've talked about a
9 lot since and that is that we regard maintaining a very rigorous
10 inspectional oversight program to be absolutely essential to the
11 success of HACCP. We, in fact, believe and our budget strategy is to
12 maintain the kind of inspectional resources in terms of numbers that
13 we have today. What we also believe is that we need to
14 fundamentally change the way in which the inspectors play their role
15 in plants and in other areas where there's an opportunity for
16 government oversight to contribute to food safety. So without
17 rigorous credible oversight I don't believe the HACCP initiative will
18 succeed. I don't think we'll achieve either our food safety objectives
19 or respond to the public's very persistent expectation that there be a
20 credible system of oversight. So the issue from the agency's
21 perspective is not whether there will be rigorous inspectional
22 oversight, it is how do we do that, what are the best roles
23 government inspectors can play in overseeing HACCP and other
24 activities in insuring food safety and meeting other consumer
25 protection objectives. I say we're going to talk in detail, both about
26 our current thinking, but then also have discussion about how we
27 ought to be inspecting under HACCP.

1 I have a question, I guess, I'd like to pose about the near term
2 interventions and just maybe raise the question by way of sharing a
3 little bit more about motivation for them and the thinking that was
4 going on in our heads as we drafted the proposals and I'll use the
5 anti-microbial treatments element as an example of this and, again, I
6 say this for the purpose of inviting some discussion and some
7 reaction. We are going to have a whole session devoted to anti-
8 microbial treatment so, again, the issue is not the details of how
9 we've done it but the concept.

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

19 But what also became evident, at least the idea that formed in
20 our heads was, there seems to be among the companies out there
21 trying to incorporate -- you know -- available technologies to
22 improve food safety. There seems to be -- at least one could assert -
23 - that there was an emerging standard of care that says that in light
24 of where we are today technologically, in light of where we are today
25 in terms of the condition of animals coming into plants, in terms of
26 the degree to which they're contaminated externally as well as in
27 some cases infected with pathogens internally, in light of the

1 practical reality of slaughter processes there seemed to be an
2 emerging standard of care that said we ought to be looking to
3 incorporate an anti-microbial treatment in the systems a way to
4 make a contribution to reducing harmful bacteria and thus improving
5 food safety. So the question we asked ourselves was well, if this is -
6 - if we're right about that, if incorporating these technologies is an
7 emerging standard of care and if, in fact, these technologies are
8 available and do make a contribution, should there be in the near term
9 as a way to begin making progress towards improving food safety as
10 we implement HACCP over the long term, the question we asked
11 ourselves should we establish -- really codify -- that standard of
12 care for the whole industry and the answer we came up with,
13 obviously, in the proposal was, yes, we should codify for slaughter
14 plants a single effective anti-microbial treatment. And there are a
15 lot of issues about whether that command and control approach,
16 which I confess it is really -- you know -- makes sense, both near
17 term and long term in light of our performance standard and HACCP
18 philosophy. But the question we're grappling with is, if we know
19 there are tools out there now that can improve food safety now as we
20 move towards HACCP and if, in fact, we can see that this emerging
21 industry standard of care to incorporate these, what is the role of
22 government in seeing to it that in the near term we make progress
23 where progress is available to be made to reduce risk and that in sum
24 and substance was the spirit and philosophy behind proposing the
25 mandate anti-microbial treatments in the near term. And I just
26 assumed -- I mean some of the discussion with us between parties
27 about that philosophical approach, I think, would be helpful to us as

1 we consider what the decision should be.

2 MS. MACKLOW: Tom, may I just make a very brief comment. My
3 recent only experience down there in Barry Marshall's country
4 demonstrated to me some very interesting things. They are not into
5 the anti-microbial treatments that we are looking at and the issue
6 becomes one of a performance standard and if they can get a total
7 plate count on their end product on a consistent basis without that
8 anti-microbial treatment there is no reason why our government
9 should be saying, okay, thou shalt do this and it is command and
10 control. They have different conditions. They don't have Nebraska
11 mid winters with balled up cattle, although two days ago I went to
12 see a plant where they did have some balled up cattle where they're
13 shaving them on the floor, but those animals had also gone through --
14 and I saw sheep going through two baths in the live sector and I had
15 never actually seen this before -- maybe I haven't been looking
16 properly when I walk around livestock pens -- but these animals were
17 literally walking through a bath and did it twice before they went
18 into a kill plant slaughtering at a hundred and twenty hour a day or
19 something. It was a substantial number of animals that were
20 actually being processed so that they brought them into that plant
21 treat. It won't work in Nebraska. Maybe Colorado. The winter months
22 for the big heavy cattle are very difficult but they had some animals
23 where they were shaving the underside of the animal on the kill floor
24 in order to once again give them that opportunity to have a clean cut
25 into the hide and to pull it away properly. There are many ways of
26 getting there and we have to decide. Are we going to be descriptive
27 or are we going to have standards that people are going to meet?

1 That's the issue. You can't have both in the HACCP system. You're
2 either going to have a prescriptive system or we're going to have a
3 meat goes in standards for certain kinds of numbers.

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

16 MR. BILLY: Ron.

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

22 I see the interventions as something that should rightly be
23 separated from HACCP as it stands -- the HACCP proposal. I would
24 make a guess to say that there's probably almost unanimous
25 consensus or unanimity among the attendees at this conference that
26 HACCP is the way to go. That everybody agrees with it as the best
27 thing in the system for improving food safety and that it should be

1 implemented. But all of the interventions and all of the, what I would
2 term, bells and whistles that have been hung on to the HACCP concept
3 are what the controversy seems to be about.

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

16 The agency, in my opinion, has a lot of work cut out for it -- a
17 lot of work -- some of it very time consuming. And much of it, I
18 think, is centered around changing the mind set of inspectors,
19 supervisors, the field people from a hands on do it yourself type of
20 control system to one of verification and monitoring which HACCP is.
21 I think the industry can do it. They are anxious to do it. They can do
22 it well if given the chance but they need a lot of guidelines, less
23 prescriptive command and control things which I personally feel that
24 the interventions are. These interventions are good and we'll talk
25 more in detail about them as they come up in the days to come but I
26 believe they are good but they should be part of a plant's HACCP
27 system and a HACCP system can well control most of the things that

1 you're trying to get done.

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

5 (A brief recess was taken)

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

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

27 The next speaker will be Dane. Dane, we can't hear you.

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

19 Back to near term measures. The note was made earlier that the
20 devil may well be in the details. There is obviously a philosophical
21 point of view here which made earlier that we see this as running
22 counter to what we want to accomplish with HACCP. HACCP is the
23 vehicle which is to get us to a safe food supply. We need to commit
24 to that, not give it tepid support and continued command and control
25 but give it full support as we move down the road. There are
26 obviously some good measures which have been identified and should
27 be probably adopted but all of those measures, as was said earlier by

1 Kim Rice, are not going to be applicable to every segment of the
2 industry and mandating them across the board returns to command
3 and control where we will be making decisions for certain part of the
4 industry where those decisions simply don't make sense. And some of
5 them, as you well know, are very controversial. The temperature
6 requirements are very controversial. And if anybody in this room can
7 tell me the difference between the risk factor associated with a load
8 of ground beef trimmed that comes in the back door at thirty nine
9 versus forty one I'd like to see that information. So there are things
10 which don't make exactly scientific sense in those measures which
11 further blur the future role of HACCP in setting up critical control
12 points and critical limits that make scientific sense. Thank you, Mr.
13 Chairman.

14 MR. BILLY: Ken. Myron.

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

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

1 that are the stickers.

2 My concern is that too much emphasis is possibly being placed
3 on HACCP. I really don't believe that HACCP is going to be the silver
4 bullet that it's intended to be and the reason I say that is because, to
5 my knowledge, there hasn't been any extensive work done on exactly
6 where most of the problem lies or where the problem lies. Perhaps
7 it's easiest to think that because food inspection is in place in the
8 meat industry that's a good place to start and that's, I think, where
9 you've started with the near term measures. But to consider that and
10 to consider what will follow as you implement all the details and to
11 think that that will be a solve all situation here I think is a mistake.
12 And I sort of have a question for you and it involves the near term
13 measures. What else is being done in the near term in all segments of
14 the food industry? I think it's unfair to single out an industry that
15 probably already has been the highest regulated in the whole food
16 chain. It's probably the strongest link in the whole food chain as
17 solving our problem. Until that can be established to consider what
18 area the food industry is, the highest risk, we may be wasting a lot of
19 time and valuable time and energy addressing the areas that need to
20 be addressed. There are -- we all know there's segments in the food
21 chain now that have currently little or no inspection at all and there
22 are areas that the ball gets dropped on and transportation -- I served
23 some of the food industry. As I said, we're in the restaurant business
24 and even struggle with employees at times understanding the food
25 business and I know there's people that probably operate restaurants
26 that maybe know how to make a steak but really don't know much
27 about the food industry, don't know much about temperatures,

1 maintaining quality control because when the product's delivered to
2 the consumer in that situation you only see the finished product. You
3 really don't see the state that it was in and so there's a whole area
4 here that I think needs to be addressed and I think if FSIS banks or
5 invests all of its capital in this one area right up front, assuming the
6 wholesale changes in this industry will solve the long lay, yeah --
7 you know -- there will be increases but will it be enough for the
8 American public? Probably not when the first instance pops up. And
9 then I think it will only contribute to the cynicism that's out there in
10 the American public already and -- you know -- I would go as far as
11 to say that people probably trust their corner butcher further than
12 anyone on this issue right now and so I think that we -- you would
13 need to identify -- and correct me if I'm wrong -- that's why I'm
14 asking the question -- identify its weakest link, go after it. It's like
15 fighting a fire. Go to the source of the fire and address it where the
16 problem lies and wait to act in a wholesale way until you know
17 exactly where you stand on that.

18 MR. BILLY: Mike may want to respond.

19 MR. TAYLOR: Your point obviously is very well taken that I
20 indicated a little earlier -- I mean we will not achieve our food
21 safety goal if we don't address the points throughout the chain where
22 hazards arise and where interventions can be made to reduce risk and
23 there are gaps in our overall system of food protection obviously that
24 outside of the plants that need attention. And we outline some of
25 those in the preamble to the proposed rules to signal where we're
26 going in terms of addressing the broad spectrum and we do seriously
27 need to address these. It includes, in our view, and we're working

1 with FDA on this, a need to determine whether there should be
2 standards -- some basic performance standards if you will -- that
3 will insure the safety of product during transportation. I mean there
4 are currently no national standards with regard to such basic matters
5 as preventing growth during transportation and that's a gap in the
6 system. We've got efforts underway to develop and need to work very
7 carefully with -- you know -- the outside communities to address
8 that. No question about it. And we also -- I mean down the chain.
9 We're grappling with how and, again, working with the states and FDA
10 on this, how to beef up the HACCP oriented approaches that could be
11 observed at the retail level to insure food to improve the way
12 products are handled there. So I mean there's no disagreement at all
13 that there are significant challenges outside the plant environment. I
14 think -- I mean our view is that we need to be working on all of those
15 areas in parallel with this initiative. We have to recognize though
16 the tools available to a federal regulatory agency are just
17 necessitate differing approaches at differing stages along the way.
18 And there's no question that we have a statutory charge from the
19 Congress that explains why we are focusing the amount of resource
20 we are focusing on the in-plant environment. Even so -- I mean even
21 within that mandate we know we need to broaden our horizon. And so
22 we -- again, as we proceed with the HACCP rule making and the
23 efforts to implement HACCP within plants we intend to address the
24 other areas. If you can obtain a set of top to bottom preliminary
25 reports you will see a number of those reports laying out ideas to
26 address exactly the question you're asking in terms of how we
27 allocate our resources outside the plants as well as within them and

1 we just wholeheartedly agree with the need to do that and we're
2 investing effort to do it.

3 MR. BILLY: Okay. Steve Krut.

4 MR. KRUT: Steve Krut with the American Association of Meat
5 Processors. I think earlier Katherine asked a question -- you know --
6 we've been nine years down the road -- ten years down the road since
7 recommendations were made and this is the rationale or the
8 justification for doing something more immediately. I think there's
9 controversy whether HACCP could be implemented over three or five
10 or eight years or whatever segment certain portions of the industry
11 might take. But I think a lot of the suggested near term interventions
12 and strategies are still very controversial and, as I say, Dane made
13 the point very, very, very strongly that many of them are not
14 necessarily in agreement from the scientific aspects. Some feel
15 some aspects of this near term intervention are economically
16 unachievable particularly maybe with the regard to the refrigeration
17 requirements, maybe the infrastructure within the industry does not
18 even allow it. I would look at what areas we could focus on that
19 would be most meaningful and I would like to suggest that as a near
20 term initiative that the training in HACCP be moved forward as a
21 number one priority. I would like to suggest as well that the HACCP
22 training be expanded a bit more than maybe just HACCP principles and
23 deal with sanitation -- basic sanitation and basic microbiology. I
24 think that is a basic training that I think really does something to
25 improve our safety net. It is very compatible with other areas in the
26 food chain, be it retail or transportation, what have you. If you look
27 at the thousand plant review over the last year -- year and a half --

1 more than -- what -- fifty three -- fifty six percent of the problems
2 dealt with sanitation. And, as I say, I think we owe our American
3 public something more immediate than a three or five or eight year
4 wait and I'd like to see us move particularly with the training
5 emphasizing sanitation as well as the microbiology and the basic
6 understanding in those areas.

7 MR. BILLY: Nancy.

8 MS. DONLEY: I'm Nancy Donley from Chicago. I'm a real estate
9 broker. I'm also might be considered by some people in this room as a
10 child killer. My son died two years ago from E. Coli O15787 poisoning.
11 I just would like to go on record as saying that consumers should not
12 be the first critical control point in the system and that we have been
13 accused too long as being the killers of our own children.

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

24 STOP's position on anti-microbial treatments -- we do not feel
25 it should be mandated; that microbial treatments emphasize post-
26 contamination clean-up rather than in-process control measures.
27 They should put also exacerbate the problem by causing very small

1 particles to become embedded in the meat and spread further.

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

8 MR. BILLY: Finished?

9 MS. DONLEY: Yes.

10 MR. BILLY: Caroline.

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

15 I think there are some food safety requirements which are
16 fairly basic. Sanitation and temperature controls sound like two
17 standards which should be basic and fairly uniform across the
18 industry. I'll be interested when we get to those, Dave, to hear the
19 discussion on those sections. But I think that there is a role for a
20 regulatory standard for things which are basic to provide a level
21 playing field for the industry. Otherwise, enforcement is going to be
22 done by every individual inspector in those plants and we can't just --
23 it doesn't work to guaranty uniformity. So I think that there -- I hear
24 a lot of discussion about command and control and we have to move
25 away from it but for things which are basic and which are uniform it
26 may actually work against the industry and against the need for some
27 basic uniformity and some standards you can rely on. To be saying,

1 oh, we don't want anything that's command and control, I don't like
2 the term command and control. There are appropriate regulatory
3 mandates and I think that's what we need in this discussion to figure
4 out what those are rather than having a knee jerk reaction against
5 anything which is mandated. I'm done.

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

9 Irwin, are you on that? Okay.

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

21 MR. BILLY: Irwin?

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

26 As far as near term measures are concerned, I only wish to
27 address that issue right now. I'd like to go into other issues later.

1 But of the four near term measures -- the micros, SOP's,
2 intervention, and time temperature requirements -- these are all
3 extremely important issues. There's no doubt that the industry has to
4 address all four of those issues. However, for anyone to mandate
5 them would be so counter productive to the overall program for
6 HACCP that you would -- you'd certainly bury yourselves in
7 bureaucracy and controls that were and will be totally hard to
8 control, ineffective in the overall program, that I think instead we
9 should be looking at those four near term measures and aiming them
10 toward our overall goal. Our overall goal is to -- and I hear it loud
11 and clear -- is to get into HACCP programs. If we can develop the
12 bases of these HACCP programs by mandating rather than the four
13 near term initiatives or measures but mandate that we all start
14 incorporating those four in pilot HACCP programs within the industry,
15 within each plan specific to plants, I think we will gain a lot more
16 stature. We will gain a lot more initiatives into improving the speed
17 with which we can all get into HACCP programs.

18 We currently have nine HACCP programs within our small
19 company because we have nine specific processes. Those nine
20 specific processes as far as bacteriologicals, guidelines, and
21 standards are concerned require several different sets depending upon
22 what we're working on. If it's raw materials coming in the door
23 that's fairly standard for most product. But as far as any other facet
24 of our operations are concerned it will vary immensely in the level of
25 bacteria that we would expect to see if we were in good control.
26 They will be aimed at different types of bacteria depending upon what
27 we are accomplishing in that process, whether it's a cooking process

1 or raw process. If it's in our cooking building we'll be looking for
2 salmonella and listeria a lot more strongly than we will in other
3 areas. We'll be looking more for our standard plate counts and our
4 cola forms to show that we're in control. Now, I'm not talking about
5 pathogens. I'm talking about measuring how well we're controlling
6 our process and that's what HACCP is designed to do. Are we in
7 control, are we doing what we say we're doing? If we can gear all of
8 these efforts toward garnering a consensus to an industry,
9 government, and the professionals that we have here -- I notice there
10 are people that represent some of the laboratories that have done an
11 immense amount of work in our industry -- if we can get these people
12 together and determine some guidelines -- guidelines -- not
13 standards but guidelines under which most plants can develop proper
14 programs I think that we will be far better off than mandating
15 anything. The same is going to be true with time temperature, SOP's
16 for sanitation. I can't believe that there's anyone in the industry that
17 doesn't have either informal or formal SOP's for sanitation if they
18 want to maintain any assemblance of good product going to the
19 customer. I don't think there's anybody in the room that's in the
20 industry that wouldn't be willing to have formalized SOP's for their
21 sanitation procedure provided that they have the means by which they
22 develop those SOP's that is plant specific and process specific. Sure,
23 there are certain general characteristics of those SOP's that have to
24 be standardized and should be standardized but you still have to have
25 a very definite program that will be differentiated by where you are
26 in your facility, what you're doing in the facility, and how you want to
27 develop your overall HACCP program.

1 As far as interventions are concerned I can't address that
2 personally. We're not in that part of the business but I think that
3 given the opportunity I think industry will come up with interventions
4 that probably will be far better than anything that we could
5 promulgate by law today. Thank you.

6 MR. BILLY: Pat --

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

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

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

27 MR. BILLY: On this point?

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

20 MR. BILLY: On this point?

21 MS. SIEMENS: Angie Siemens with Oscar Meyer. I'd like to
22 address Caroline's specific question on I think we've got a problem
23 with some definitions of what we consider command and control. In
24 our viewpoint, command and control and what we see in applying
25 these to the near term initiatives we could also use the word
26 prescriptive without flexibility and that's where I see command and
27 control and our definition. We use anti-microbial treatments in our

1 processes. We have two different turkey facilities. We do not use
2 the same process in both facilities because we have different
3 equipment, we have different raw products that come into those
4 facilities. What we are seeing is going back to a statement that Mr.
5 Taylor made. He was looking to codify a single effective treatment.
6 That is the problem that we have with the current command and
7 control. There is not a single effective or several effective as the
8 regulation came through that was very specific in a very -- you know
9 -- three or four types of treatments that we would be allowed to use
10 under the current proposal. We use chlorine in our chillers as our
11 treatment and we feel that that is very effective in our processing to
12 control and meet the same goal that you're headed to but it's not in
13 the regulations nor is there a flexibility for that type of treatment in
14 addition to other technologies that could be available. That's what
15 we disagree with in terms of command and control were we not given
16 flexibility to fit various treatments to our processes to achieve the
17 ultimate goal of safe products that we have.

18 MR. BILLY: Mike.

19 MR. TAYLOR: Let me just clarify what I was meaning to say
20 about what we proposed. It was not to mandate a specific anti-
21 microbial treatment but to say that the proposal was that plants
22 should have one effective anti-microbial treatment. In the proposal
23 identified some that are based on data we've got and believe to meet
24 some standard of effectiveness but the idea was to -- we're talking
25 about the idea that we had in mind was that the standard -- the
26 requirement would be to have an effective anti-microbial treatment
27 and -- and I think we hypothesized as that meaning effective for a

1 one log reduction but then it would be -- we would be any -- any
2 treatment that met that standard would meet the requirement. We
3 had simply, based on what we knew, identified several that we
4 believed met that standard.

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

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

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

26 MR. TAYLOR: You know -- it's very good that we got a chunk of
27 time set aside on this issue just as a sort of signal of where our

1 current thinking is. We are not the least bit wed to the specifics --
2 you know -- as written in the proposal. On this particular issue, we
3 think as a general matter, is desirable as I think most people in the
4 room agree, it's desirable for folks to be taking steps that are
5 available now to take to reduce pathogens and -- you know -- we are
6 completely open -- you know -- as to the manner in which we
7 accomplish that and I think the session we've got on anti-microbial
8 treatments is an opportunity to talk about that and what kind of
9 flexibility is appropriate, what the appropriate linkage is to some --
10 you know -- more pure performance standard, but it's the objective
11 that I think we're going to keep our eye on and I think not to get on
12 that particular issue, we are not the least bit wed to the details of
13 what was in the Register. We ought to be talking more when we get
14 to the subject. I mean that's -- let's talk about what the
15 possibilities are.

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

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

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

1 you know -- that's a detail that makes a lot of difference.

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

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

19 MR. BILLY: Okay.

20 MR. JAN: Lee Jan with Texas Department of Health and
21 representing NASDA. I agree with the last comment or two. One log
22 reduction from what and if we are looking at anti-microbial spray to
23 reduce and we know where we want to get to and if that happens to be
24 a one log reduction then I think that mandating anti-microbial
25 treatments to get there when someone's other -- someone else's
26 other process may already be there is where we're getting too much
27 command and control. I mean there may be -- you may not need -- if

1 we have some standard and that's the problem. If you're saying you're
2 going to change the wording to satisfy Oscar Meyer so that they can
3 use whatever treatment they want but you're still saying they have to
4 have a treatment why not change the wording where you can use a
5 treatment and allow and authorize and don't get in the way of
6 treatments but don't say you have to use a treatment. I have concerns
7 that number one, ineffectively applying treatment may add bacteria
8 or use of the wrong equipment or add residues or you may have a
9 contaminant just like -- lot more -- when you start adding you have
10 chances of adding stuff that you don't want to have remaining on a
11 carcass. Also, we've seen reports of where adding some sprays may
12 actually increase the survivability of the pathogens. So there are
13 things I'm not real comfortable about mandating something that might
14 lead to be a problem but I would also not want to stand in your way so
15 that would be -- that would be where I might see the changes -- you
16 know -- look for a target to get to but don't say exactly how to get
17 there. Thank you.

18 MR. BILLY: Dell.

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

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

1 assure you, anybody that violates our rules and regulations and I have
2 that authority.

3 The only thing I would like to tell Nancy, I would love to be able
4 to tell her that I'm never going to endanger another child with E. Coli
5 015787. I cannot do that. It's much like being in the middle of a
6 Kansas thunderstorm and knowing that lightening is going to strike
7 somewhere but trying to be able to predict where it's going to strike.
8 That's about how effective we are at knowing where that organism is
9 or where it will show up. If we do a test and find that that product is
10 clear the only thing that I know is that one small sample that I tested
11 is clear. There's a ninety nine percent probability that it could still
12 be in the load that I tested. That's how ineffectual our science is in
13 this whole area right now. Specifically, to near term treatments,
14 acid based rinses, we've got several problems with them. Number
15 one, all bacteria are not bad, believe it or not. We threw out three to
16 four years ago tested lactic acid rinse in our Dodge City plant and it
17 proved very effective at reducing micro flora on carcasses. Well, in
18 the one log to better range so we started using it. Had approval to
19 test it and use it. We were going along in great shape and all of a
20 sudden for every action there is a reaction I'm told and sure enough it
21 happened. We created a whole different problem in our plant -- the
22 environment. All of a sudden we had gas blow ups in bags. We had
23 spoiled beef in bags and what we had done, we had removed the
24 competitive micro flora from our carcasses to the extent that
25 Lactobacillus grew rampant in the cooler environment. So we had a
26 tremendous problem. The only way I would use an acid based rinse is
27 if I could follow it with a chlorine rinse. I can't do that because we

1 have to export to Canada and our people that buy from us, like Oscar
2 Meyer that make lunch meat and all that, they have to export to
3 Canada. You can't export to Canada if you hyper-chlorinate your
4 water. Hyper-chlorination in Canadian terms is more five parts per
5 million. So it's an effectively -- you know -- it just doesn't work.
6 We cannot -- and there are other countries that have other
7 restrictions on export product. We don't know when carcasses are
8 going through the slaughter floor which parts we're going to export or
9 which carcasses we're going to export. We can't segment them. The
10 export market, believe it or not folks, is a tremendously important
11 market to the domestic livestock industry in this country. We've had
12 a wreck in prices this year and a lot of people are in trouble who
13 would have been in much greater trouble without that export market.
14 So that's another obstacle that we have to mandated, if you will,
15 prescribed anti-microbial treatment.

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

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

24 MR. BILLY: Sure.

25 MS. DONLEY: I just want to say that consumers -- I appreciate
26 your condolences and my condolences to you and your loss --
27 consumers are a lot more savvy than given a lot of credit for. We do

1 not expect guarantees in anything in life. What we do expect is that
2 everything possible is being done before it gets into our hands, into
3 our supermarkets, and into our restaurants. Do we have a
4 responsibility? Yes. Once it's into our hands and once it's to the
5 restaurants and other establishments have a responsibility? Yes.
6 We're looking at farm to table chain of responsibilities but right now
7 not everything is being done to make sure that it is in the best
8 possible condition by the time it gets to us and, as I said before, it is
9 unfair of industry to make consumers be the first critical control
10 point in a system at the very end of the chain. That's the point I want
11 to make.

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

13 MS. DONLEY: No.

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

16 MS. DONLEY: We do not at this point in time have anything done.
17 I'm going to speak specifically now for O157. There is nothing being
18 done except just very, very recently has the USDA started doing a
19 random sampling for O157. Five thousand tests, half of them in retail
20 establishments, half of them in plant capacities. This is just
21 something that's very, very, very recent.

22 Another point here is, if industry is going to take the position
23 that consumers be responsible for the product then industry better
24 darn well be getting out there and telling in no uncertain terms to
25 consumers what it is they're dealing with because let me tell you,
26 they don't know. And it is your product and you need to stand behind
27 it and be responsible for it that if once it gets into the public's hands

1 there might be a problem. It should be spelled out loud and clear that
2 unless you take every single precaution that in handling this product
3 and that little tiny label doesn't cut it. But in no uncertain terms and
4 unless you cook this to death and say a prayer you are endangering the
5 lives of your children. And industry for obvious reasons has not
6 chosen to take that route in educating consumers.

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

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

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

1 command and control. I don't see this as prescriptive. I see that
2 language as encompassing what you were saying.

3 MR. BILLY: Jim? Patrick?

4 MR. BOYLE: Thank you very much, Mr. Billy. I'm Patrick Boyle
5 with the American Meat Institute and I would just briefly like to
6 comment upon some of the concerns and points that Mrs. Donley
7 raised. In terms of the responsibility industry or, in your mind, the
8 failure on the part of industry to make consumers aware that they too
9 are part of a comprehensive food safety chain. You, on a couple of
10 occasions, have made reference to the fact that it's unfair for
11 consumers to be first critical control point in a food safety chain.
12 You do have a role to play as consumers, and for raw product, whether
13 you're preparing it in a food service establishment or in your kitchen,
14 you are a critical control point, particularly for the pathogen E. Coli
15 O15787, but for pathogens in general because for raw products to
16 date the only thermal step that we have available is cooking but there
17 are a number of other steps or critical control points that are
18 available to us well before the product reaches the retail store or the
19 food store or service establishment or the kitchen itself. A lot of
20 those steps have been researched and proposed and presented to FSIS
21 and many of them have been implemented over the last few years as
22 we become more aware of the risk associated with E. Coli O15787.
23 Since the outbreak in the Pacific Northwest, my organization as well
24 as a number of other specific companies and in cooperation with the
25 universities have conducted millions and millions of dollars of
26 research and we have developed intervention strategies that are
27 demonstrating to us our ability to reduce pathogens in general and

1 further reduce the incidence of 015787. Use of steam vacuum
2 technology, use of carcass rinses, either by themselves or in tandem
3 with other rinses. We're experimenting with the exposure of
4 carcasses to intense pulse light that reduces pathogens. They are
5 intervention strategies but they are not thermal steps that cooking
6 is. It is not a thermal step like irradiation is which is pending before
7 the FDA for approval for its use on beef. Until there is that thermal
8 step on raw products it is appropriate and indeed necessary for all of
9 us to be aware of our role as a critical control point and for cooking
10 as the final critical control point in that whole chain of farm to table
11 food safety. In order to better educate consumers there have been a
12 lot of efforts in that regard. The government itself has mandated
13 that the label that you refer to, and by itself, admittedly that may not
14 be enough but it's part of industry-wide education program, I think's
15 an important intervention strategy, if you will. Similarly, my
16 organization, in cooperation with retailers and food service
17 organizations, developed within a few short weeks after the Jack in
18 the Box incident in the Pacific Northwest more comprehensive safe
19 food handling brochures that have been reproduced and distributed in
20 retail stores throughout the country, all part of the educational
21 program. The FSIS hot line is part of that consumer education
22 program disseminating information about our responsibilities. But
23 HACCP itself is, while not a panacea, if we get it right and get it in
24 place will provide us with greater controls to reduce pathogens in
25 general and that's why it's so important that we move as quickly as
26 we can in that area. But to suggest that industry is not doing
27 everything it can is contrary to what we are actually doing in our

1 plants every day and to suggest that we are passing the buck, if you
2 will, to the consumer as the first critical control point is not an
3 accurate characterization of how we see our own role in the chain nor
4 how we see the role of the ultimate food preparer in the chain.

5 MR. BILLY: Okay. Bob.

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

16 MR. BILLY: AI?

17 MR. OSER: Alan Oser from Hatfield Quality Meats. I've been
18 dealing with USDA personnel now for about twenty five years in the
19 plant in Washington and generally arguing with a lot of people back
20 here over those years. The philosophical problem that we're facing
21 now with these prescriptive regulations to understand it you have to
22 realize that the -- we've come to a crossroad here. Up until the point
23 that USDA began getting very serious about HACCP the industry
24 controlled food safety by compliance to regulation. It's important to
25 understand that. The FSIS dictated what food safety was through the
26 issuance of regulations. In a HACCP system you define food safety
27 through a hazard analysis which is an on-going process. The

1 regulations -- I'd only use the term don't count -- but they're
2 immaterial to a certain extent. What is important is your hazard
3 analysis and this is where these two things conflict and this is why
4 we're having the problem with it. Let's get specific on carcass
5 washes. The agency issues a regulation which is what this will be.
6 You have to have a carcass wash. You put it in. That carcass wash
7 represents the agency's view of how you get carcasses in a sanitary
8 condition. Their stamp of approval is on it. We have presented in
9 another USDA form -- I won't go into it in great detail -- a system
10 that prevents contamination on carcasses. We have shown that to
11 over time to give us a three log reduction in bacteria. Here's the
12 problem. This is a competing technology. It has nothing to do with
13 wash cabinets, nothing to do with stainless steel. If you're operating
14 in a hazard program you have the prescriptive requirement that to
15 satisfy this problem of contamination on carcasses you must have the
16 carcass wash or you're not going to move to the other technology even
17 though it may be out there. If, however, you come to because you have
18 to have -- excuse me -- you've got to have a carcass wash -- have to
19 have it -- it's there, it's in the regulations. If you come to the
20 conclusion through a hazard analysis that the only way you can get
21 your carcasses and be sure your carcasses have a low enough level of
22 bacteria to satisfy whatever the standard is going to be, fine, you put
23 it in. If another technology comes along that's better than that, fine,
24 you take it out. If it's part of the regulations you're going to have to
25 get a regulation polled. A lot of us can remember the last -- an
26 administration that was quite busy in the 80's philosophically didn't
27 happen to like the idea of publishing regulations period which meant

1 you couldn't be regulated because you had to publish a regulation to
2 get the other regulation out and one of the hardest things to do is to
3 remove a regulation which you're into, right? You can appreciate that
4 because that stuff can be horrendously misinterpreted that you're
5 dropping the ball at any point you try to repeal a reg. And this is
6 where we philosophically have a problem on this issue. We need to
7 decide which way we're going here. Are we going to define food
8 safety through regulation, or are we going to define food safety
9 through hazard analysis? They are different.

10 MR. BILLY: Joe. Carole.

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

26 MR. BILLY: Ron.

27 MR. PRUCHA: Mike, you know in my response to your -- I would

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

27 MR. BILLY: I have Jim and Dane and Carole. So, Jim.

1 MR. LOCHNER: You got a question for me?

2 MR. BILLY: Dane?

3 MR. BERNARD: Thank you Mr. Chairman. Dane Bernard, National
4 Food Processors Association. I listened with interest to the last
5 segment of this debate. The philosophical difference that was talked
6 about earlier I think Alan Oser put it very succinctly as to where that
7 leads us. Let me make clear as was made clear in our comments, we
8 are certainly not against baseline criteria. The National Food
9 Processors Association nor any other reputable organization is going
10 to go out and say there should be standard operating procedures on
11 sanitation. There should be. We support that. And we're not
12 replacing throwing out everything that's in existence now, a point
13 that Mr. Gilbert made earlier. There are elements of existing
14 regulations which are very compatible with HACCP and would be
15 rolled right in -- the cooking guidelines on roast beef, cooking
16 guidelines on chicken. A lot of things will roll right in here so we're
17 not throwing everything out. We're not starting fresh with HACCP.
18 There is a concept that the Canadians labeled prerequisite programs
19 and I think that is our concept of where you begin. There should be
20 solid programs in place supported by appropriate rules that mandate
21 good manufacturing process and they are already there to a certain
22 extent and if they're not then we need to fix those holes if there are
23 holes. But when we say we're going to take up HACCP and build on the
24 safety record that we have and make it better and we're going to
25 utilize HACCP, as I've said before, then we begin to look at everything
26 with a light as to how to support that. There are elements of the
27 interim measures that were proposed that possibly should be, if not

1 adequately treated in separate regulation, should be done so, but
2 those which are more nebulous in terms of the science behind them
3 and the broad implications and I think if it's been said -- you know --
4 nobody here that I've heard supports every element in every operation
5 of what was proposed in the interim measures. So I think if I could
6 lend my own impression to this, if we decide at the end of the day
7 that the agency needs to mandate interim measures definitely there
8 should be sunset when we hit HACCP. Those which form those
9 baseline programs, the prerequisite programs should be dealt with as
10 such and should be the place we start and the foundation upon which
11 we build our HACCP program. Thank you, Mr. Chairman.

12 MR. BILLY: Carol?

13 MS. FOREMAN: Thank you. I'm Carol Tucker Foreman. I served as
14 Assistant Secretary for -- with responsibility for meat and poultry
15 inspection from 1977 to '81. I would really have preferred to hold my
16 comments until we began discussing performance standards. It might
17 have eased this discussion we're having now had we started the
18 discussion with performance standards because I think some people -
19 - Angie, Dane, Alan Oser -- have made some good points about that --
20 about the difficulties with some of the interim proposals. On the
21 other hand, the objective of the meat and poultry inspection program
22 is food safety. It is to provide a safe product to the American public,
23 the safest possible product to the American public and for that the
24 taxpayers spend six hundred million dollars a year and in return the
25 industry gets a little stamp that says to the public your government
26 has examined this product and says that it meets their requirements.
27 That's a very serious obligation. With all due respect, it's more

1 serious in my mind than that that goes along with your label on it, Mr.
2 Dryden, because although your label clearly connotes quality that is
3 not true across the board and a lot of products are sold without labels
4 and it is that government label on there that says to the public this
5 meets a standard. I'm in favor of HACCP but Dane and I have had this
6 discussion over a long period of time. HACCP, once it becomes part of
7 a government regulatory program is not the HACCP that you have in
8 your plant. If you want to have HACCP with no performance standards
9 then in my mind it can't be part of this government program. If the
10 government is going to have the inspector put a stamp on it that says
11 this product meets the public's standard for safety then you have to
12 have a performance standard attached to your HACCP program. It
13 stops being quality control to meet your needs for process control of
14 meat the plants need and becomes therefore part of the public's need
15 to protect human health and that requires some sort of performance
16 standard in the end. I would be prepared to forego specifics on some
17 of these interim measures if there were a way to initiate
18 performance standards at the end of the line in their place.

19 MR. BILLY: Rebecca.

20 MS. HOLLAND: Okay. I'm Rebecca Holland from Kansas City,
21 Missouri. I'm a processing inspector. I've been in the food inspection
22 for seventeen years and many of you -- listening to you I wish I was
23 working in your plant every day. You care. The ones that we have the
24 problem with are those maybe other twenty six plus thousand we have
25 right now. We're short staffed. We have up to twelve plants a day.
26 We may do pre-op. This plant may have a QC program. Okay. They're
27 taking care of themselves so okay, I won't go there. I won't have to do

1 pre-op this week. Okay. I go next Wednesday. And it takes him two
2 and a half hours to get the place cleaned up to operate. Those are the
3 things that we're concerned about when if you -- you know -- we feel
4 that these other plants take care of themselves and it's something
5 that we see every day. Granted, the majority of -- I'd invite any of
6 you to Kansas City anytime. We have great barbecue there. But in the
7 majority care, they do run a good program but we need to -- the
8 HACCP concept is good but we need to intertwine with what we've
9 got. We can't give up. You just can't throw everything out. You've got
10 to put it together and I just want to comment on -- you know -- the
11 forty degree. You have a guideline. We have some common sense. You
12 know -- we don't have to put it in dog food. I'd like to comment later
13 if I could. Thank you.

14 MR. BILLY: Tom.

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

16 MR. BILLY: Rosemary?

17 MS. MACKLOW: I think Inspector Holland made a valuable
18 contribution that would be worth looking a little behind what she told
19 us because it may help us to understand how the system now either
20 works or fails us. She said that she -- you know -- went in and it
21 took them two and a half hours to fix the place up and that they were
22 a company where they can QC program. In my experience, a company
23 with a QC program like that, we'd have a sanitation program and there
24 -- depending on how large or small they were their foreman might
25 have gone through his standard operating procedure checklist to look
26 at the kinds of things that she was looking at. Maybe the general
27 manager does this once in a while and yet the day she was in it took

1 them two and half hours to fix it up. I wonder if she could tell us
2 what kind of action she took to make sure that they don't just clean
3 up every two weeks again; that they do it on an on-going every day
4 basis; that if they've got a QC program they are held accountable to
5 meeting that and does she go and look at their records and say now I
6 found this machine unacceptable, but you looked at it every day for a
7 week and a half and you found it acceptable. Now I'm going to hold
8 you to my standard which is that there be no bits of fat or no smears
9 or whatever it may be. I wonder if she could give us a little bit
10 behind that one cause I think it would be useful to better understand
11 where those responsibilities lie.

12 MS. HOLLAND: Okay. Thank you, Rosemary. Since then -- okay --
13 with that course the -- the department was tagged -- the plant was
14 tagged off. They proceed to clean with cold water. The QC -- the lady
15 that was in charge of QC said well, we're ready. I go out and I
16 checked it again. And I said, I'm sorry, you're not ready. I talked to
17 the manager. I asked him why his program wasn't working. Well, the
18 sanitation group that we've got in here cleaning, they're just not
19 doing their job. And then I asked him if this -- you know -- what
20 would they have done had I not been there that morning. And,
21 Rosemary, I didn't get an answer. Since that time though we have
22 increased the pre-op sanitation. This is a processing plant. We have
23 increased the sanitation. They have changed their -- you know -- as
24 often as we do the pre-op we've increased that or we did that for
25 about -- for a certain length of time. They started -- the plant
26 manager starting giving the QC person more authority and they can
27 clean up with hot water in the morning. There's -- then we have --

1 when we went back in to recheck this program they have -- they have
2 straightened it up and like I say they have changed their sanitation
3 people that they have coming in at night to do the clean up. So does
4 that answer your question?

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

14 MS. HOLLAND: That's right.

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

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

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

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

1 MS. MACKLOW: You shouldn't have to.

2 MS. HOLLAND: That's right.

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

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

17 MR. WATSON: I'm Clarence Watson from San Diego. I'm an
18 inspector. I've been an inspector for fourteen years and just to
19 support what she's saying, there are a lot of plants as TGC and what
20 we call they pencil whip you with their documentation. Now we do
21 pre-op sanitation on a daily basis but they are random samples so the
22 plant does not know where you're going to come in. The total quality
23 control plant -- when we go to that plant our first notification to
24 plant manager is that we're going to do a pre-op, are you ready, and
25 when they respond yes, then we go. We look at their documentation.
26 We find out there's everything acceptable. But when you get to the
27 plant we are finding other things. We're finding rusty equipment,

1 plant maintenance is not being right so we are seeing that industry is
2 not living up to their responsibility. Now there are directives to take
3 this plant out of total quality control if they're not performing and
4 it's called progressive enforcement. Now when we document repeated
5 deficiencies then we are documenting -- we write speed memos to
6 our circuit supervisors to inform him that this plant is out of
7 compliance, they're not living up to their responsibility. That's our
8 only way to get them out of that total quality control system. Now
9 that system and the plant likes the system because it has the emblem
10 and it's a special emblem to the public. That means they are above
11 USDA requirements. But it's that inspector's job in the plant. He's
12 the eyes and ears of the public and if you're going to couple that with
13 HACCP that inspector has been in there daily because what we're
14 finding they're just pencil whipping us to death and it's not going to
15 work. We are there for consumer protection. That's our job. Thank
16 you.

17 MR. BILLY: Irwin?

18 MR. MUSKAT: I'm Irwin Muskat, Jack Pack Foods. I think we're
19 back again to what is it we want to achieve here. If you want to set
20 up standards all over again and double and triple the number of
21 policemen that we're going to need to enforce those standards then
22 we're going to be back to where we were, where we are, and further
23 that even more mired in the same type of policies that we're
24 enforcing on the industry today. If the end result is to have clean
25 meat going out the door and safe product going to the consumer what
26 you want to be measuring is what were the results of the plant's
27 sanitation program, what did they factually tell you and what trend

1 analysis is available to show whether they are improving their status
2 or not. You have factual information available to you through the
3 technologies that are available to us today. If you're going to use that
4 factual technology that's going to measure how well you're doing and
5 the government is going to be able to come in and verify that your
6 numbers are, in fact, what you say they are, then you do not have an
7 honor system as was alluded to before. You have a system that is
8 documented and verifiable by the overseeing Department of
9 Agriculture to make sure that you're doing your job as you stated you
10 would do it. If you're not, then you have to impose rules and
11 regulations that will enforce you to either do your job or you don't
12 belong in the business.

13 MR. BILLY: Dennis?

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

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

1 a performance standard means to the agency, as least under current
2 thinking. Thank you.

3 MR. BILLY: Thank you.

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

17 Performance standards also have a broader role though and,
18 again, as I mentioned earlier, we'll have a whole -- I mean all of
19 Friday is on this subject. There needs to be, in our view, a
20 performance standard to serve as a measure of accountability for
21 controlling and reducing pathogens that deals very directly with the
22 issue of what's an acceptable level of food safety performance when
23 it comes to reducing pathogens on raw meat and poultry products
24 because that, having some measure of accountability for that, is what
25 gives power, in our view, to HACCP as a systematic science-based
26 way to control processes in order to meet an appropriate standard of
27 performance, so we see a critical role for performance standards and,

1 in particular, when we complete the transition to HACCP it seems
2 essential to the integrity of that and to the effectiveness of it as a
3 tool for improving food safety to be some standard of performance
4 for harmful bacteria on raw product.

5 #3 MR. JOHNSON: If I could follow up. I'm going to put words I'm
6 thinking in Carol's mouth then I apologize. I think she was referring
7 to, in effect, an end product standard as opposed to the individual
8 performance. I don't know if she was or wasn't.

9 Hi, Carol.

10 MS. FOREMAN: I was.

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

14 MS. FOREMAN: I want more than trend analysis.

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

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

27 MS. FOREMAN: Tom, can I -- this is Carol Tucker Foreman again.

1 Mike, you raised the notion of clearly in order to get to HACCP
2 throughout the industry there's a period of time involved and we have
3 to do something in the meantime. Dennis and Mike -- Dennis, I
4 thought I heard Mike say something about a finished -- about an
5 interim step might be a performance standard for some of these SOP's
6 -- the interim proposals. Do you like that? Before your clients kick
7 you, answer.

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

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

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

19 Dennis --

20 MR. BILLY: Identify your --

21 MR. POCIUS: I'm Joe Pocius with the National Turkey Federation.
22 Dennis broached one subject so I won't belay that. I do want to
23 comment though. There seems to be an unfortunate repetition of an
24 unfortunate sound byte that has made it into the press and that is
25 that HACCP will do away with inspectors in the plant. Dane
26 mentioned earlier that that's just not the case and that's not the
27 intent. We cannot operate without inspectors to do the monitoring as

1 per HACCP. We need someone in there to do that. That does not
2 obviate the presence of inspectors in our plant and I would hope that
3 if an inspectors sees a load of meat which they suspect to be
4 contaminated they would tag that. That's part of their job. That
5 should not change under HACCP. This sanitation issues that Rebecca
6 mentioned should not change and there is a monitoring section within
7 an SOP program as well. I guess there is a disconnect here as to what
8 role the inspectors will play. Certainly it will change. Certainly
9 there will be a more efficient way of operating. But just as certain
10 their presence will be there. We need to get to that and get off of the
11 "A" here, Mr. Billy. We spent an awful lot of time. I've been biting my
12 tongue cause as we go on we have no choice but to start to discuss
13 the details of this under a section which we're supposed to just speak
14 of generally. So I'm sure we'll all jump in and discuss it further
15 later. Thank you.

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

17 MR. SYRING: My name is Art Syring. I come from Springfield,
18 Missouri. I'm a federal meat inspector. I had the privilege of working
19 for ten and a half years as a relief inspector across the State of
20 Missouri. I also had the privilege of being in an Oscar Meyer plant for
21 the hot dog portion in Missouri. They have a full TQC. I worked in
22 plants where poultry plants have NELs. Turkey plants have NITS and
23 it all comes down to one thing. I don't care how good you are, it's only
24 how good you back your system. I find a lot of fabrications of records
25 and in the NELs programs they'll go out there and they'll do these
26 tests and this is all plant-generated procedures and policies. It's not
27 government. The plants set their own programs and then they can't

1 afford to follow them because they're too strenuous and they cause a
2 restriction on their operations and they have to slow down. Time is
3 money in industry. It's not in inspection. I'm a consumer advocate. I
4 work for the consumer and I'm proud of it. When those consumers
5 come and says what are you giving me to eat I want to say I gave --
6 the plant gave them the best money can buy, not government. We're
7 only there as eyes for the consumer to monitor your processes, not
8 our's. When you establish this HACCP program that we're all sitting
9 here talking about I want to be proud too because I want it to enhance
10 what I do, not take away. I want to be there with you, I'm for you,
11 let's go with it, but let's enforce it and let's not just make a paper
12 chase again like we did on everything else. That's all I got to say.

13 MR. BILLY: Okay.

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

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

21 (Luncheon recess was taken)

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AFTERNOON SESSION

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

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

16 MR. BILLY: If you look at the agenda for today we had quite a
17 discussion about near term measures and I understand there are
18 probably many more points that could be made. In that regard, we
19 walked right up to -- the sense I had was we're warming to get on
20 with the specifics in that regard. We also talked about HACCP and
21 there were some very broad statements of support. We've talked
22 some about merging HACCP in the current system. There will be more
23 coming up on that this afternoon. We did not talk at all about timing,
24 agency implementation, and industry adoption. There were some
25 statements about that and the need for transformation and so forth.
26 My suggestion -- what I'd like to do is to hold off on timing and the
27 more I've thought about it, it might be a good topic for the last day

1 after we've talked about a number of the other things. I don't want to
2 ignore it and I think it's important. There are a lot of very good
3 comments and suggestions about timing in all the comments we've
4 received but I'm going to move that to the last day and get on with the
5 next area which is FSIS oversight of HACCP and the changing role of
6 inspectors under HACCP. In that regard, hopefully all of you have
7 received when you signed in a paper -- a discussion paper titled
8 Overview of HACCP Proposal, FSIS Oversight of HACCP and the
9 Changing Role of Inspectors Under HACCP. This paper is designed to
10 do several things. It does not do other things and I just wanted to
11 talk a little bit about that before we get into the specifics. If you
12 look at that paper, under Roman I there's perhaps in little different
13 words there's a characterization of what the original proposal --
14 what the objective was -- with regard to this area, what the
15 objection was. Roman II -- Description of Comments -- is sort of in
16 capsulation of the comments but there's a very important point. This
17 summary of the comments is not designed to summarize all the
18 comments we've received with regard to these subject areas. Rather
19 it's in capsulation or summary of the comments that are associated
20 with the key issues that come out of all of the comments or that
21 were suggested during the scoping session that we had. We will, in
22 fact, in the final rule address all of the comments received. We've
23 read them all already, we've got summaries of them, and no comments
24 will be ignored. What we've tried to and what was agreed to, a few
25 pages, is to highlight and give a sense of the comments as they relate
26 to some of the key issue areas to facilitate the discussion so I
27 wanted to make that clear.

1 The next section deals with current thinking on selected issues
2 and this is where the agency now in trying to move the ball forward if
3 you will is identifying what it's observing as points or concerns that
4 must be addressed and some options or approaches to addressing them
5 and that's what this paper is designed to do and hopefully will
6 facilitate the discussion and the understanding in terms of these
7 areas in terms of inspection under HACCP and the role of inspectors.
8 To further that, Bill Smith is with us and Bill is going to highlight
9 some of the key points that are in this paper as a precursor then to
10 having a very specific discussion and answer questions about the role
11 of inspectors and inspection under HACCP.

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

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

19 Under validation, what we're looking for is to determine the
20 credibility of the plan, whether it be an SOP or the HACCP plan that it
21 will be used as the operating mode in that plant. As, for instance, in
22 a sanitation SOP, the regulation proposes specific areas that should
23 be covered in a sanitation SOP such as the cleaning of equipment, a
24 preoperational sanitation inspection to check the effectiveness of
25 that cleaning, who will be responsible for perform those activities
26 and where they would be identified. And then in an operational mode
27 that, again, there is a responsible official to identify and react to a

1 direct production contamination situation, whether it's
2 environmentally from equipment or facilities or from personnel,
3 either in personnel hygiene or a plant employee's production handling
4 of the process that's going on. We would then be looking for the
5 inspector then on the first day that the SOP is to go into effect to
6 take a look at the plan that the plant has and compare that against
7 that criteria and if those major areas are addressed in the SOP that's
8 what we would see as a validation effort. And the same thing for the
9 time temperature. The anti-microbials, while they don't require
10 written plan, there is in the proposal those specific uses and, again,
11 the inspector would be determining that the use that has been chosen
12 in that plant meets the regulatory requirements. In the HACCP plan,
13 again, we've gone on. In the proposal it talks about that the plan
14 should be developed along the same principles and so the veterinarian
15 or inspector in that plant again would be looking to see that a hazard
16 analysis was done, that a critical control point has been established
17 to control that hazard, that a critical limit has been identified for
18 that critical control point, the monitoring activity has been
19 described, record keeping has been described, that if there's a failure
20 at that critical control point that there's a method for dealing with
21 corrective and preventive action, and then, finally, a plant
22 verification activity to insure that the monitoring activity in the
23 critical control points and critical limits have been met. We see that
24 as validation and therefore if those seven principles have been
25 addressed in the HACCP plan then that would be the basis of our
26 validation and that establishes the credibility of the plan. Once then
27 you've established that the plan is valid, whether it be an SOP or the

1 HACCP plan then you -- we would see ourselves moving into a
2 verification mode.

3 Verification mode we see being conducted under two basic
4 procedures. One would be record review of the CCP monitoring
5 activity and the plant verification activity. And then we would see,
6 for lack of a better word right now, hands on activity, where through
7 direct observation, either visual or performing a task or observing
8 the plant performing a plant verification task, that the inspector
9 would actually take a sampling of CCP's and see that they are in
10 control or that there would be a sampling of the plant verification
11 activities again to determine the process that's been identified and
12 the validated plan as being followed. That removes us then from a
13 detection mode to a process, monitoring, and analysis mode and that's
14 how we see ourselves in the regulatory arena and that was
15 recommended, I believe, by the National Advisory Committee, micro-
16 criteria for food. That would be an appropriate role for a regulatory
17 agency. And the enforcement arena then we are looking at, again,
18 with SOP's or the near term initiatives that they would be in place on
19 that first day that the regulation -- ninety days after the final rule
20 as it proposed now. And that failure to have those in place would
21 result in some kind of suspension action until that basic criteria was
22 met and the same thing with the HACCP plan that if the first process
23 01 that's identified in the regulation is -- should be in place twelve
24 months after the final rule and, again, if a HACCP plan is not in place
25 then we would see ourselves taking that same role -- that we'd
26 suspend that particular process until that particular criteria was
27 met.

1 Under the verification inspection, inspectors, again, would be
2 monitoring to see that the plant is following their SOP or their
3 HACCP plan and so, again, we would not be in the mode as earlier
4 described this morning. Like in Kansas City, we would have expected
5 the plant to conduct the pre-operational sanitation in that situation
6 and have identified direct product contamination situations and if
7 they had controlled those we have no deficiency at that point because
8 the SOP specifically states if there's something wrong and the plant
9 takes the action to correct it we do not have a system failure at that
10 point. We have a system that's operating and that's a major change --
11 that we're not going to jump in right away and take the action that
12 we're going to expect the plant to follow their SOP and take that
13 action. The same thing with the critical control point and monitoring
14 in a HACCP plan, for instance. If we have a poultry product being
15 produced and the cooking temperature is a hundred and sixty and the
16 product is pulled out at a hundred and fifty eight but the plant
17 employee recognizes this and tags that product and holds it, puts it in
18 the cooler for further analysis of what's going to happen, then the
19 plant through a process and authority or some means determines that
20 the time temperature was adequate or that it has to be recooked at a
21 certain time temperature in order to make that product meet the
22 critical limit and the plant does that, again, we have no deficiency
23 because the plan is working. What we will be looking at is to take
24 action when we determined the plant fails, and, again, let me just
25 give a quick scenario, both in the SOP arena and the HACCP arena as
26 an example.

27 Let's say that we have a small operation that -- HRI operation -

1 - and that they're vacuum packaging for raw pork loins and it's the
2 end of the day and an order comes in for five fully cooked hams and
3 the production foreman is responsible for the SOP in that plant and
4 that he instructs the employee to into the fully cooked cooler and
5 bring out five fully cooked hams and vacuum package them. Well, he
6 then observes the employee going in and doing that without changing
7 their clothes, without washing or sanitizing their hands, bringing
8 those cooked products into a raw product area without washing or
9 sanitizing the equipment and then proceeds to vacuum pack that
10 product and that is the responsible official for the SOP and the
11 inspector observes that then we would be in the mode there to
12 determine that we had a failure of the SOP resulting in retention of
13 those five fully cooked hams and rejection of that equipment and then
14 the corrective action that we would be expecting in that situation is
15 not just to wash down the equipment but to correct the failure of this
16 SOP. This gets to what Rosemary was saying this morning. Do we fix
17 the individual incident which has been our past history or do we take
18 a systems approach to deal with the incident but also to put
19 something in place to prevent it from reoccurring. The same thing in
20 a HACCP situation. In that situation I was talking about where we
21 cook the poultry to a hundred and sixty and let's say it was on a timed
22 cycle in a smokehouse and the time cycle was met and the production
23 employee again pulls that product out, does not observe or document
24 even though that was the monitoring activity described in then plan,
25 that the product did not meet temperature and go ahead and pushes it
26 into the cooler and then it goes through its normal process and let us
27 say the production or the shipping foreman has been identified as the

1 person who would do the plant verification activity which would be
2 review all monitoring records on the CCP's and then any sampling that
3 was done prior to shipment and the product's on the truck ready to go.
4 Again, an inspector after doing a process review determines that it
5 did get through all those steps and no action was taken then we have
6 -- we would see a HACCP plan failure and, again, the regulation as
7 proposed now would suggest that we would suspend that operation for
8 fully cooked keep refrigerator products and that the only correction
9 for that would be, one, to deal with the specific product, but, two, the
10 HACCP plan would have to be adjusted to address that process failure
11 and have to be revalidated then again to get back in operation. So we
12 see ourselves looking at taking a systems approach, a sampling, a
13 record, or hands on activity or combination thereof to determine
14 whether the system as described by the company is working or not
15 and if it is, including taking corrective actions when a problem goes
16 wrong because we know that plants are not going to work at a hundred
17 percent compliance all the time. Things happen. But if the plant is
18 initiating action to address those situations then we have no
19 deficiency again or no process failure. What we have is system
20 compliance. On the other hand, if they're not, then we feel that would
21 be our role to act in that situation. And so basically that is the
22 foundation for -- for how we would be acting in that -- in a SOP or
23 HACCP plan environment. Again, basically validation to see that the
24 plan is being used, whether it be the SOP or the HACCP plan is
25 credible, meaning that it meets either the requirements of the
26 regulation or has met the seven principles and then to verifying the
27 once you know you have a credible plan verifying that that plan's

1 being followed and taking action when you either have direct product
2 contamination or a systems failure. And we understand that is a
3 move from where we have been in the past. We understand that we
4 have a lot of work to do as supervision in that system. We understand
5 that there's a training process that has to go and we are looking at
6 changing the way we train to insure we can equip our employees with
7 a just in time concept that when near term initiatives come on that
8 they be ready to deal with those specifics, that when they need to
9 have validation expertise that, again, they will be equipped and able
10 to do that and when they go into the verification mode, again, that
11 they be equipped to do that. So basically in a broad sense that is
12 what we are thinking about right now for validation and verification
13 and enforcement of both near term initiatives and HACCP plans.

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

15 MR. DONOVAN: Hello. I'm Mike Donovan from the Association of
16 Supervisory Technical Professionals and one of my questions to you,
17 Bill, on that particular scenario that you just laid out on the case of
18 the chickens being cooked, pulled out of the smokehouse, for instance,
19 and put in the cooler at a hundred and fifty eight degrees, when would
20 the inspector take his action? Does he have to wait until it goes on
21 to the truck or how is that going to be set up? Because I can see
22 where there could be a situation -- I'll just play devil's advocate --
23 that the individual rolls it into the cooler and the inspector notices
24 that and he doesn't take any action and he goes to tie up the product
25 and the company says well, I just didn't get around to put it in my
26 records yet and I can see where that could end up being a situation
27 where the company is saying that the inspector was over zealous and

1 the inspector said, well, they had no intentions of doing this and
2 controlling the product. How are we going to handle situations like
3 that one?

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

21 MR. BILLY: Okay. Joe and Dell.

22 MR. DUFF: I'm Joe Duff, an inspector from Indianapolis, Indiana.
23 And I just have a couple of points of contention I wanted to make and
24 the first is to find a ground that we can all agree on and that's that
25 the worst plant manager in the world is your inspector. But you keep
26 giving us a job. And quite frankly I don't want the job. I didn't apply
27 for it and I really think you need to take control of that situation and

1 run your plant and stop giving it to us. We have a very specific
2 function that we perform there. It's well defined. It's not a secret.
3 And if we're operating outside of those guidelines we have other ways
4 of dealing with -- internal ways of dealing with us and so we're
5 pretty much under control quite to the contrary of thinking some. I
6 also wanted to point out that the issue's made of inspector using
7 common sense, I just wanted to make the point that at one point this
8 year when an inspector used common sense to make a judgment call
9 and give the plant a chance to correct that problem he was accused of
10 bastardizing the system because he didn't make an issue out of it,
11 just gave them a chance to correct the problem. I'm saying, where are
12 you standing on these issues? You want us to write it up? You want
13 us to give you a chance to correct it? The call is your's but you're not
14 taking it. I think the ball is in your court and you just don't want to
15 dribble it.

16 MR. BILLY: Dell?

17 MR. ALLEN: I'd like to get the electricity on down there. I think
18 we need to broaden inspection's role in that HACCP format, Bill. And I
19 have the opportunity of being with a company who has representation
20 plant-wise on both sides of the border, being Canada and U.S. And I
21 know you all are well aware of what's going on in Canada. In our
22 Canadian facility -- and first of all we have fully operational HACCP
23 plans in all of our facilities -- we started in 1991 developing. We
24 developed, we wrote, we implemented, we redeveloped. And that's
25 the thing I think we need to all keep in mind. The whole part of
26 HACCP is a very dynamic thing. It changes -- in some cases,
27 weekly/monthly as things change in the plant and I think that needs

1 to be kept very definitely in mind. But on the Canadian side, the IIC in
2 Canada there in our plant, she sits as a sitting member on our food
3 safety committee. She deals with us as we deal with the HACCP plan
4 in that plant. She's a contributing member to it -- a very valuable
5 contributing member to it. All of the ag Canada inspectors -- we
6 have a training session for every employee that walks through the
7 door on HACCP, on food safety -- very basic in nature to the hourly
8 employee. Those with additional responsibilities get additional
9 training. They go through that training with our people. It's a very
10 cooperative situation because we are in it together folks -- the
11 inspection force and ourself. I mean whether it's one of those things
12 that we can have a fruitful relationship as long as we will contribute
13 to it and make it that way. And I'd like to see this side of the border
14 at least consider that approach. We have invited that type of
15 participation in the States and very honestly have not gotten
16 favorable response to it on the agency's part.

17 The other thing I'd like to say is that everything we do needs to
18 be made as objective as possible because invariably when it's
19 subjective we get into very deliberate arguments. We have individual
20 private companies right now that HACCP is happening around us,
21 whether we want it or not, it's happening. We have for the last two
22 years had enumerable audits from various people that we supply
23 product to that come in and audit our HACCP plan and they give us a
24 score. It's a numerical score -- numerical rating. We have an in-
25 house system that does the same thing. If we have a plant that
26 scores a ninety or above in our internal audit that plant gets to get by
27 with less audits than the one that scores below that. It's a very

1 workable system. It's a very objective system. But in order for
2 people to go in and intelligently perform that audit they have to know
3 and understand what they're looking for in the HACCP system and we
4 would hope that the agency would take advantage of those
5 experiences of people like the fast food people in this country who
6 are already doing this thing who have people who are actually trained
7 in that area -- you know -- as you adopt your own plan. I think it
8 would move us all down the road a lot faster.

9 Finally, one more objective thing. On pre-op sanitation it's a
10 bug of mine. We have an internal system that's very objective and yet
11 subjective. It's combined because microbiology is a -- I'm a pseudo
12 microbiologist. And I'm beginning to wonder if there is true
13 microbiologist by the way. But we have a system where we track the
14 pre-op sanitation program with microbiology. Every piece of contact
15 equipment they have in the plant on the kill floor is identified in the
16 computer. We random sample it. We test five percent of those daily
17 and we track the microbiology on that system but it's three days
18 after the fact -- always is -- because of microorganisms being --
19 and microbiology being what it is. In addition to that then, we have a
20 visual system that goes with it and we score a certain percentage at
21 random and the two are combined into an objective score and lets us
22 evaluate objectively our clean up crews that clean up. I've offered
23 that, again, that program to the agency on a couple of occasions and
24 invited you to come out and see it in operation. Yet to see anybody
25 come to do that. But that invitation is still open. And I would love to
26 -- to me this is the mode that we've got to get inspection into. And
27 that inspector -- I fully agree with everything that the other people

1 have said. We need third party presence not because they're bad guys
2 but because when you work in a facility day after day after day you
3 tend to get barn blind. And you need that additional set of eyes. You
4 need those people coming in and pointing out where you have been and
5 gotten barn blind. And, again, to me, that's how the agency needs to
6 really function and help us cause you can be a great help to us. And I
7 would really implore that you go north of the border and talk to the ag
8 Canada people in seriousness of how they have approached this whole
9 issue. They will have their system fully going by October of next year
10 and it's been a very cooperative effort between industry and ag
11 Canada. It's really a treat to work with them. Thank you.

12 MR. TAYLOR: Dell, if I just make ask a question to follow up.
13 There's some very legitimate but competing interests or
14 considerations in what you're saying. I mean one is obviously we need
15 to work together and learn from each other and there's a lot that can
16 be done collaboratively to address -- to make progress on food safety.
17 On the other hand, one of the things that we're seeing a need to do and
18 part of the thrust of our program, frankly, is to more clearly
19 delineate responsibilities between the plant and the inspector and
20 clarify some of the lines that have become blurred and which through
21 the combination of command and control approaches to regulation and
22 our inspectors perhaps taking -- you know -- by default or otherwise
23 taking more responsibility for management of plant operations than
24 they ought to in the end the concern is that under the current system
25 as a function of the system not clearly delineating responsibilities
26 and maintaining the distinction between the plant responsibility and
27 inspector responsibility, neither the plant nor the inspector is doing

1 the best job that a plant can do in producing safe food and that an
2 inspector can do in providing oversight. And so we're frankly looking
3 to maintain that distinction. And my question, I guess, is how do --
4 do you think that's a good idea and if it is, how do you maintain that
5 distinction in the Canadian model where you posit -- you know -- the
6 IIC sitting on the company's food safety committee? I mean how does
7 that work as a practical matter in maintaining some distinction
8 between roles?

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

1 it for us. I'd bet that with your experience.

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

9 MR. BILLY: David.

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

13 I feel like I'm a little bit wedged in here out of place because I
14 didn't realize we moved off the near term objectives and we skipped
15 "B" part of that. But maybe what I'm going to say will also help with
16 some of the things we're talking about. If we look a little
17 introspectively at what's happened in the canning -- in the meat
18 canning industry I would say the USDA and the industry has not taken
19 credit for having a HACCP program in effect for nearly ten years. You
20 talked about these things came out in 1985. 1987 the canning regs
21 were put into effect and essentially if you look at every aspect of
22 that canning regs we have a HACCP program that we've had to live by
23 for those years and I shouldn't say live by. We have joined in on this
24 and as the National Meat Canners Association years before that we
25 were working with the Department to develop things like how do you
26 evaluate abnormal containers, what do you do about process
27 deviations? These were things that we worked on as an association

1 with industry members and your Department to develop what is an
2 abnormal container. When you see it what do you do with it, how do
3 you react, what are the standards, what do you do, is one-tenth of a
4 percent too many, is half a percent too many, and what is the
5 proposed standard that we should have? And we developed together
6 all of those things and they culminated in this regulation that we
7 have. Also, in conjunction with that, almost every major canning
8 plant in the United States has a total quality control program that
9 says in essence we accept the responsibility to control the program
10 that you approve for us. And there is a working relationship of
11 inspectors in those plants. We've worked that out. I happen to have
12 been the plant manager of the first total quality control program that
13 went into effect in the United States. It was about 1984 with the
14 Dial Corporation in Ft. Madison, Iowa -- canning plant. We sat with
15 the inspectors and it was a very difficult time for all of us. I was a
16 young buck saying, hey, you know, I'm in control of this place and the
17 inspector in charge says it's my responsibility. Until we finally sat
18 down and talked and worked in conjunction with like what he's talking
19 about in Canada, the thing wasn't working properly. But we have
20 those things in place. You ought to take credit for it. My God, you've
21 had it for almost ten years. What we're saying is, the National Meat
22 Canners Association is you ought to look at that and say, hey, there's
23 no need really to change what we're doing with canning. You have it in
24 place. Don't lay some more things on -- when I talk about layering I'm
25 saying I've already got the HACCP program, why give me any more.
26 Our safety record is very good. Consumers know how to look at a can
27 and tell you whether it's a problem. Unlike a piece of fresh meat,

1 those microbes hide in there. In my can, they swell up and blow up
2 and they leak and they do all kinds of things. So I think you should
3 look beyond us. You should accept that you have a HACCP program and
4 we're running it and maybe you ought to step back and look and see
5 how the inspector, the plant, and the control systems are working
6 already in conjunction with the canning industry and the total quality
7 control programs in there and I think you'll get good clues about how
8 this system can work and we're more than happy to work
9 cooperatively with you to show you anything we're doing.

10 MR. BILLY: Merle?

11 MR. PIERSON: My name is Merle Pierson. I'm here on behalf of --
12 --. I'd like to address the overall -- -- (microphone not working).

13 -- -- all very critical issues. The role of regulatory is in
14 verification and we agree with most of the points that were
15 presented here by Mr. Smith. There were some nuances in terms of
16 definitions that I think need to be worked out -- verification,
17 validation, auditing. Hopefully, the National Advisory Committee can
18 clarify some of those terms further. A very key issue is how do you
19 develop and implement this system. It's just not a wholesale
20 immediate change. I think that would be a very serious mistake.
21 Number one, industry has to have in place effective GMP's. They must
22 be in place. So we support the concept of standard operating
23 procedures for sanitation, etc. I agree with the earlier comment that
24 in fact what's probably needed is a separate trading program relative
25 to GMP sanitation. I would agree that that, in fact, should be done in
26 conjunction or cooperation with the agency. Quite frankly, industry
27 and regulatory need that common understanding. And this is where it

1 takes us to HACCP. I had the opportunity for the egg products people
2 in USDA before they came into FSIS to do four HACCP workshops for
3 egg products and those workshops included both inspectors and
4 industry. And it was an interesting change in mindset in both groups.
5 The beauty of HACCP is it offers a commonality of understanding. We
6 should know where each other's coming from. And we don't need to
7 separate that. I think it's a great value when you have that training in
8 conjunction with each other because then each group understands
9 better their roles and where each other's coming from. Very
10 important concept too. We just can't develop HACCP plans. We need
11 to go beyond just how do you write a HACCP plan. The question is,
12 how is that plan implemented? And it's not a wholesale
13 implementation. It's an incremental implementation and generally
14 it's one critical control point at a time.

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

26 MR. BILLY: Irwin?

27 MR. MUSKAT: Irwin Muskat, Jack Pack Foods. Bill, I'd like to

1 address this to you but before I get to that part. I want to address
2 something that Dell Allen said. In our HACCP programs and tied in
3 with our ISO programs we publish charts that show our PDR's, our
4 performance deficiencies by department, by category, by inspection
5 personnel. We publish that. We post that for all of our employees to
6 see. We offered through local inspection and all the way up to my
7 personally speaking to Tom Billy that if it was available to us we
8 would have our inspection personnel in our own training programs for
9 HACCP and ISO. I gathered that through political and public probable
10 problems that did not come to prevail. But our QA Department has
11 told me they do not report to any executive other than the QA
12 executive when they have to do something with product that is other
13 than its original intent. But all of that comes down to the fact that
14 we're a TQC plant and I think our initial date was 1981. The biggest
15 problem that we ran into with TQC and that I see from what I
16 understand from what you've discussed, Bill, is that we are going to
17 be just one step off of traditional inspection. In order for a HACCP
18 program or any program like that to work you have to be able to verify
19 that the program in its entirety works, not just at one critical
20 control point. When the inspector has the option to step into the
21 middle of the program and make a value judgment that the program
22 isn't working the inspector has basically defeated the entire concept
23 of the program in that the double checks and triple checks, whether it
24 be the person that's in charge of the program or the validation of
25 paperwork has never had an opportunity take effect. And, yes, so this
26 time he stops at a critical control point number 3 and next time he
27 may stop at a critical control point number 1 but every time he stops

1 at a critical control point you've never found whether in fact the
2 program is working properly. If you're not going to allow the product
3 and the process to go to its full extent and then decide what you're
4 going to do with it then you haven't -- you really don't have a HACCP
5 program. That doesn't mean that the inspector shouldn't document
6 that he found a deficiency at a critical control point. Of course he
7 should document that. And I would think that any good program would
8 have some kind of a rating schedule that if the inspection personnel
9 came in and did an audit function and found that at certain critical
10 control points we have weaknesses then we have a weakness in our
11 program that has to be addressed but you can't make a determination
12 that the program itself fails verification because of that and I see
13 the traditional inspection -- as I said -- just one step away.

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

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

1 those results we would make a determination whether the process is
2 in control or not in control.

3 On the validation, again, we go back and what we'd be looking
4 for in a start up situation would be that the seven principles have
5 been addressed, that a hazard analysis has taken place. We're not
6 going to be making a determination on whether -- whose method of
7 hazard analysis -- whether it's an appropriate or a valid hazard
8 analysis. We want to see that a hazard analysis has taken place. We
9 want to see the critical control points then for the hazards that have
10 been identified that they are controlled at some point in a critical
11 control point. Again, it's not up to us to say whether that critical
12 control point should be there or not be there. If the plant has
13 established it to control that hazard then we will be following that.
14 That a critical limit has been established and let's say somebody
15 roasts pork has established a critical limit of 148 degrees at a
16 seventeen minute hold and at ninety percent humidity that results in
17 a 5-D reduction and you call 015787 and 70 and salmonella. We're not
18 going to be asking our veterinarians or inspectors to determine
19 whether that's adequate or not. What we are going to be asking them
20 to see that there's some support in the form of scientific data that
21 the plant -- that has to be assembled in the HACCP plan -- something
22 there to support that. And those are the kinds of things that the basic
23 seven principles have been addressed. If our inspection personnel
24 question whether a CCP is appropriate or a critical limit is
25 appropriate we're going to provide them a mechanism to get that to
26 the science and technology people within the agency who have the
27 expertise to make that determination and then after that

1 determination then we would -- I would see some action being taken
2 if we're not in agreement. But we're not going to have the in-plant
3 people making those kinds of determinations other than, like I said on
4 that critical limit, we would expect some -- whether it's evidence of
5 a heat penetration study -- some kind of evidence to support that
6 critical limit unless we're using regulatory requirements that exist
7 now. So that essentially is what we'd be seeing at least at start up.
8 You know -- down the road we would be equipping our people to be
9 able to make those calls but at this point that's what we would see as
10 initial validation activities.

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

23 MR. SMITH: Absolutely. That is what we would be putting or
24 that is our thinking now to get into training because of the system's
25 approach because -- because if you look at the proposed enforcement
26 action which is suspension of that process you have to have
27 documented evidence that we have a system failure and so we need to

1 inspect such that we'd have the evidence to support an action of that
2 nature. So we would be teaching or training our people to take a
3 system's approach, both in record auditing and direct hands on and we
4 are working with -- as suggested we'll work with all auditing
5 agencies but we have been working with a number of other federal
6 agencies that have expertise in auditing the records to build a case or
7 to make a determination from a number of observations and we're
8 looking at a lot of the industry to help us and what are those tolls
9 that we use in record auditing and direct observation and statistical
10 analysis to be able to make a call when a number -- if a number of
11 CCP's fail then can say the process is in question. And I agree that
12 the plant needs to be allowed to have their plant verification activity
13 take place and so if that calls for a review by the QA at the end of the
14 day on each lot that the CCP's have been met then that has to be
15 factored in to determining whether you have a system failure or not.
16 And I agree. We would need to be documenting the specific incidences
17 but that is not a systems failure.

18 MR. MUSKAT: One last point. Still on your subject matter. If
19 inspection assignments are going to basically remain similar to the
20 way they are now and there's going to be an inspector in every plant
21 you're not going to be taking advantage of HACCP and what HACCP is
22 designed to do and I heard -- maybe I inferred it from the
23 conversation -- but if a smaller plant -- maybe a huge plant is going
24 to need an in-house inspector to be able to do the audit functions I
25 would never even do it that way if it were my choice. It would only
26 be audit teams going around and all the inspectors would be on audit
27 teams and they would be either announced or unannounced audits

1 going through these plants to verify inspection. And if you want to do
2 -- this is the way we're audited now by ISO. This is the way we're
3 audited by AIB. This is the way we're audited by all of our suppliers
4 and our customers. Excuse me. Not our suppliers. MR. SMITH: We'll
5 take that as a way -- I think what we need to have the activity drive
6 -- what we do in those plants -- and that's a good suggestion.

7 MR. BILLY: Art?

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

10 MR. MUSKAT: I didn't say that.

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

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

16 MR. SYRING: Less than a full time. You don't understand right
17 now that in ninety percent of our plants on patrol assignments -- I
18 patrol three plants and those three plants under the old system -- I
19 work with a five hundred percent workload. I'm not in that plant full
20 time anyhow. When I come into that plant I find several deficiencies.
21 Somebody's out of bed. It ain't me. These programs that you're
22 writing you have to understand you set the standard. I'll say it again.
23 Just like under sanitation. The plant -- the one plant that I go into
24 has run a perfect low deficiency swab test on sanitation. They swab
25 every morning. You go out there and you see them swabbing the whole
26 place. The plate count is zero. You look inside the equipment or the
27 people's equipment they're dirty. They're not clean. They're

1 unsanitary cause they have meat scraps, particles, residue from prior
2 day's production. They'll form all this stuff down, they'll take their
3 sanitizers, pull the top, and we go look at your record and it's perfect.
4 The only way we're going to know to protect the consumer to know
5 what we're doing is actual verification and that requires us to come
6 to your plants. Right now, under PBIS, we're assigned how many
7 times we visit your facilities -- twice a week. You're supposed to
8 have responsibility for five. My computer tells me I'm going to be
9 there on a random basis. It doesn't tell me when I'm going. It's
10 selected weeks in advance. And you're telling me you don't need
11 inspectors. If you got problems you do need inspection. You need a
12 good enhancement with HACCP over inspection to work together in
13 unison to make a good program work for the consumer. That's the main
14 deal here. We're all sitting here wanting to better ourselves. You
15 wanting to better yourselves to make more money, produce a
16 wholesome, clean, and sanitary product for the consumer. I want to
17 make sure the agency gets their money's worth when I'm out to
18 working.

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

1 with a fine tooth comb and verify that we are doing what we say
2 we're doing.

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

15 MR. BILLY: Lee? Caroline?

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

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

21 There are a couple of things you said that really are great
22 concern to me. One is that you're going to go through a checklist to
23 make sure that the companies comply with the seven principles of
24 HACCP. And then you said later that the in-plant inspectors wouldn't
25 be reviewing the adequacy of that hazard analysis or the PCP
26 identification or the critical limit or anything else. Somehow that is
27 going to be handled in Washington. How is that going to be handled?

1 My second question is you said that once you've gone through
2 this checklist that this would be validation of the plan by FSIS. In my
3 book, that's simply doing hazard analysis without any assessment of
4 whether they've done it correctly or whether they've identified all the
5 hazards with their product is not validation of the plan and I would
6 recommend that the agency consider instead the validation being by
7 FSIS of those plans include both a review of all of the elements of
8 HACCP together with the adequacy of that review -- whether the
9 plant has actually identified all their CCP's and whether they've
10 identified appropriate critical limits and appropriate monitoring
11 activities, etc. together with microbial testing to validate that the
12 hazards identified are actually being controlled for. And I am
13 reminded of USDA's pilot program where they found in the after
14 implementation of HACCP in poultry plants that some pathogens
15 actually increased in the products rather than going down. So I think
16 that microbial testing has got to be a critical part of the FSIS
17 validation of those plans.

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

22 And my final point is that you have said that sampling -- that
23 before you found a failure of -- a systems failure -- and please
24 correct me if I'm wrong -- or a program failure that you would have a
25 failure more than one critical control point. It is my understanding
26 that a critical control -- a failure of even one critical control point
27 is enough to introduce contamination into a product or increase levels

1 of contamination into a product. It was my understanding that a
2 program failure would be a failure at a CCP together with a failure to
3 take corrective action. So my question to you is did you mean -- did I
4 misunderstand it that you had to have a failure at more than one
5 critical control point?

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

26 Again, on the CCP, as I was discussing earlier, I think you do
27 have to look at a number of -- well, let me first agree that a CCP by

1 definition that one failure that we have by definition of a critical
2 control point that you may have a hazard introduced at that point.
3 What I think you've said the key was and I agree that failure of
4 corrective action. So monitoring activity has to be allowed at least
5 to take place to identify that failure would be one, and, again, plant
6 verification activity also includes monitoring -- independent
7 monitoring of those CCP's and/or micro testing and those are the
8 checks upon the checks in order to make sure that the product is safe
9 and I believe what Mr. Muskat was saying earlier that if you stop it at
10 that point then you -- then the system has not been allowed to work
11 and so there is, I agree, a fine line and a public health mode when
12 inspectors see that a product has failed a critical control point, of
13 course we're going to act. Whether we're going to say that is a
14 systems failure, all that has to be factored in and that's the task that
15 I see us having to train our people which is very difficult. I see that
16 the task of the industry also. But making that determination when we
17 have a systems failure as opposed to one specific point. That is not
18 to say it's not important. I would say that one of the most important
19 things that comes out of the HACCP plan is the plant verification
20 activities which would include sampling. Now as far as our sampling,
21 I did not mean to indicate that verification activity would include
22 review of records or auditing of records, hands on, and we do plan to
23 do some sample verification. We're doing that now in our pathogen
24 and for salmonella and E. Coli O15787 and fully cooked products and I
25 don't see that changing. But that's in addition. We're already doing
26 some of those so some of the things we're looking at, at least for
27 start up, is how do we take existing programs and use those in the

1 verification mode so I would see our salmonella -- our roast beef
2 program being used as sample verification for a roast beef HACCP
3 plan.

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

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

14 MS. DEWAAL: I would agree with you.

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

1 So there are three checks.

2 MR. BILLY: Ron?

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

5 I think or I feel very strongly that the agency must go farther in
6 this case than it has proposed. I find very troublesome -- well, one
7 of the tenets of inspection has always been unilateral -- what I
8 would term uniformity of inspection -- that inspectors in New York
9 are essentially doing the same inspection procedures as the
10 inspectors in California and everywhere in between. But I find
11 somewhat troublesome, Bill's outline, in that the identification of
12 critical control points would be left to plant management and their
13 respective IIC in each plant. For uniformity of inspection I think that
14 may well be a disaster. Critical control points to me are just fact
15 and they are critical and failure in any one or more of them can well
16 lead to the potential of human health illnesses and problems. I would
17 recommend -- I've given this one a lot of thought -- but I would
18 certainly recommend that the agency continue on the path that they
19 took several years ago with the HACCP pilot plant test and all of that
20 but they convened workshops to come up with generic HACCP plans
21 for each -- for several types of products. Ground beef was one. I
22 think poultry slaughter was another one that was worked out and
23 critical control points were identified. I would go through that or go
24 through a procedure similar to that with the cooperation of industry,
25 possibly validated by the National or Micro Advisory Committee or
26 something like that but come up with a set of critical control points
27 that everybody agrees to that really are critical for every type of

1 process that we do, whether it's canning or ferment sausage, or
2 cooked sausage, but the major varieties of processing and slaughter
3 that occur. These ought to be given to the industry. These are the
4 basis. These are the minimal critical control points that you can have
5 if you choose to make sausage, for instance. You can have twenty or
6 twenty five control points -- any number you want -- but you've got
7 to cover those for uniformity of application and uniformity of
8 consumer protection.

9 MR. SMITH: Let me just address some of that real quick. I did
10 not once indicate that the inspector in the plant management would
11 be passing final judgment on the critical control points. What the
12 inspectors we hope to teach were that of the hazards identified that
13 there must be a controlling place somewhere to control each one of
14 those hazards and that failure to have a point to control those
15 hazards will then mean we do not have a valid plan. And there is a lot
16 of work going on now, I believe, to develop generic plans and make
17 those available. But to mandate critical control points would take
18 the flexibility, I think, because I don't think we could cover every
19 operation out there. We've already heard with the hot boning has
20 different circumstances and to identify minimum. We will be
21 teaching -- I mean we do have to teach our folks that on a cooked
22 operation that there must be a kill step or further a product that is
23 suspected to be pathogen free because it's ready to eat there must be
24 a kill step and then there must e a maintenance of that kill step and
25 we go into the thinking and the teaching and the guidelines we'll be
26 giving our people. But I think -- you know -- to come out and say
27 there must be a kill step when -- of this nature or that nature -- I

1 think the plants are in the best mode to determine those. It's our
2 responsibility to have our inspectors recognize them and then if they
3 are not adequate to be able to react to that situation.

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

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

18 One of our roles, as Bill said, will be to validate HACCP plans
19 and the validation of a HACCP plan is more than a checklist exercise
20 and clearly on the issue of the hazard analysis, which is the critical
21 first stage of developing a plan, we have to be able to know and make
22 some assessment of whether a plant has, in fact, in an acceptable
23 way, identified the hazards because that's what the whole plan is
24 built on. Obviously, to do that, we are going to have to provide
25 guidance to our employees and I think and their intention is through
26 generic HACCP plans and perhaps other means we certainly need to be
27 letting the industry know what we regard to be hazards in a

1 particular processing, particular operations that certainly need to be
2 taken into account in designing a plan and so we are going to have to
3 have the tools available to our inspectors and, again, working with
4 industry to be sure that HACCP plans are addressing the hazards in
5 any particular process that need to be addressed and we're not going
6 to just leave that to the ad hoc decisions of inspectors or leave the
7 industry without guidance.

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

22 MS. MACKLOW: Tom, it seems to me we keep talking in the --
23 like I've said -- HACCP seems to be like jello running through your
24 fingers. Could we ask someone in this room that has a HACCP plan to
25 cook sausage just tell us what their critical control points are in
26 their production? Would that be helpful to sort of make it somehow
27 real to people to understand a little better?

1 MR. MUSKAT: May I read one but not on sausage?

2 MS. MACKLOW: Sure. Cooked sausage?

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

4 MS. MACKLOW: Cooked product?

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

6 MS. MACKLOW: Is it cooked, Irwin?

7 MR. MUSKAT: Cooked meatballs?

8 MS. MACKLOW: Meatballs. Okay.

9 MR. MUSKAT: Critical control point one -- receive meatball
10 batch, label packaging materials. And I'm reading off of the flow
11 diagram and you just check and see whether that meatball batching
12 information, labeling, packaging passes inspection. If it does you go
13 on to forming meatballs. You're at critical control point number two
14 when you form your meatballs you check your inspection checkpoints
15 at that point, your measurements, your testing, your ingredients to
16 make sure that everything there has passed. You go to cooking as
17 critical control point number three. And then you go to your last
18 critical control point in the process itself. Now we're only talking
19 about in process critical control points and that's into the freezing,
20 packaging, and labeling. In order to do that you have to have a
21 program -- safety program that tells you what you're going to do and
22 what your critical control point is, what you're going to do for
23 measurement of hazards at that critical control point. I could read
24 those. There are biological hazards, chemical hazards, and physical
25 hazards. You're going through employee habits, GMP's, equipment
26 condition. At critical control point one you're going through
27 temperatures at critical control point one. You're going through meat,

1 age at critical control point one. Foreign objects, damaged
2 containers, contaminated packaging material, incorrect preprinted
3 labels for a scheduled time runs, and then you go to two and you do
4 basically the same type of thing, including maintenance PM on
5 equipment to make sure you haven't got foreign material that's
6 coming from equipment that's not properly maintained.

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

8 MR. MUSKAT: On that one process.

9 MS. MACKLOW: On that one process.

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

11 MS. MACKLOW: Yeah, okay.

12 MR. BILLY: Alan?

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

1 initiative in food safety.

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

10 But what I really wanted to say was these HACCP programs are
11 by nature non standard programs. The agency -- I understand Dr.
12 Prucha's logic. It's FSIS logic. I think it's a little bit of a holdover.
13 That's understandable. You've been there. It's a non standard program.
14 FSIS has a real problem with non standard stuff. And the reason for
15 it is that -- you know -- you have a large field force and it's very,
16 very difficult for the field to work with non standard programs. Now,
17 if I go back in history a little bit. When Ms. Foreman was -- you know
18 -- sitting in your seat more or less we took the first or the last great
19 leap forward you could call it and got into TQC -- a non standard
20 program. However, it was realized at that point that we just can't
21 throw our inspectors into this non standard field here. They're going
22 to require some intensive training and that training was -- you know
23 -- not -- you know -- I don't want to belittle what was in documents
24 here, but it wasn't the amount of videos or in-plant site, it was go
25 down to Texas for a week or whatever it was and really get into how
26 do you inspect a TQC facility and in the first few years in the -- well,
27 a little bit longer than that -- I guess the late 70's into the early 80's

1 we had an interesting thing taking place where plants that were
2 getting into TQC. The inspection attitude was one of partnership. It
3 was one of cooperation. There was a great deal of sharing of
4 information and disclosure taking place and it was generally non-
5 confrontational but it was a nightmare from the standpoint of
6 inspection plans because each inspection plan had to be based on a
7 TQC plan which was different in every single facility. And I'm sure,
8 or Bill, you must have been right in the middle of that at that point --
9 you know -- it was a nightmare to try to keep up with these things
10 and every time a TQC plan was amended -- you know -- you amend
11 your plan of inspection. So the Department came out with an ISG,
12 PBIS and away went the customized plans of inspections for TQC
13 plants. They had a variant on traditional inspection but basically it
14 was the same plan except you monitored more and you verified a
15 little bit less. You got into two parallel inspection systems. Then in
16 the 80's -- you can tell I've been in the industry too long -- then in
17 the 80's you started to get a drift of where the roles became more
18 and more adversarial, where the inspectors were being told look, you
19 guys are not the plant sanitarians -- you know -- you're not managing
20 the plants, your job is go in and identify deficiencies and the plant's
21 got to figure out they're going to get out of it. And it seemed to take
22 away this idea of partnership anymore. The inspectors are supposed
23 to identify, define deficiencies in the plant, they're supposed to take
24 the responsibility -- was the big key word -- clean it up. But we got
25 into a very adversarial role and we're still in that role.

26 #4 I'm curious -- you know -- from -- you know -- Bill I know has
27 been there through that whole thing -- you know -- Dr. Taylor, you're

1 a little bit new to that. We have a much bigger problem now. We're
2 taking an entire industry and putting it into a non-standard program.
3 How do we put together an inspection program, how do we train
4 inspectors to deal with completely different HACCP formats and so
5 forth that are going to be out there? One of the easy ways to do it is
6 to standardize everything but if you do that you're the guys running
7 food safety then.

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

23 What we would see ourselves then doing is moving away from
24 the ISG specific product task now so as the process comes up those
25 tasks that are specific to raw ground beef in the first process comes
26 under that right now we have approximately seven CCP's in the ISG
27 devoted to raw sausage, hamburger, other raw products. There's

1 approximately -- and then all the receipt and storage and activity
2 that goes along with that. Because of that we'd be covering those
3 under the process inspection. We would probably be turning off -- we
4 will be turning off those other tasks so we take away the process
5 specificity. But now we go from tasks that took five or ten minutes
6 that may take inspectors an hour to complete because now they need
7 to look at the entire spectrum in order to make a systems
8 determination. So that's a little bit of the thinking about where we
9 are today and how we transition to where we're going tomorrow. The
10 uniformity -- again, I keep coming back is to the seven principles and
11 then we train our people to recognize what a critical controlling
12 point is. The plan must define what the critical limit is. And
13 therefore you now have your standards even though they're specific to
14 that plant. You have a standard that you would verify that critical
15 control point being in compliance by the critical limit established by
16 that plant. And we would target our inspections based on those.

17 MR. BILLY: How about training?

18 MR. SMITH: Training, again, what we're looking at training-wise
19 and, again, we're trying to use that just in time concept, that we
20 would have specific training on validation and verification and
21 enforcement activities for near term and we're looking right now at
22 at least -- at least a week that we'd be taking and developing training
23 and taking that to inspectors and veterinarians and supervisory
24 personnel. Then we'd see another training segment that would get
25 into the principles or philosophies of HACCP, the principles of HACCP.
26 That's where we'd be training them to do hazard identification,
27 critical control point identification, critical limit. Those particular

1 activities of how you build a plan and we would devote -- right now
2 we're looking at at least a week to that activity. And then there's a
3 third activity when the process actually comes on line. According to
4 the schedule laid out in the regulation would be in-depth training on
5 verification and validation activity and enforcement of those -- those
6 activities. Along the lines of what we've been talking about here and
7 so we'd have three specific training packages that one is completely
8 devoted to near term and then two to HACCP and that's what we're
9 looking at right now in order to equip our personnel to be able to act
10 in a HACCP environment and then deal with this non-standardized that
11 you discussed but by having those seven principles and having a
12 critical control point, a critical limit, and monitoring activity and
13 the records required, that, I believe, is where we get our
14 standardization, at least to build an inspection system off of.

15 MR. OSER: I'd like to make one suggestion, Bill. It may not play
16 too weak with some of the inspectors out there but because the
17 training's going to be very difficult to accomplish and because you're
18 putting an in-house inspector in a -- in what could be a precarious
19 position. In other words, if a guy's out there and you're telling him he
20 has to validate a hazard analysis, he has to validate a HACCP program,
21 and the guy may not have had a whole lot of training in HACCP. It
22 doesn't sound like the agency can afford perhaps to give him a whole
23 lot. Rather than have him operate in that vein, have him, number one,
24 verify that or validate that a hazard analysis does exist, number one;
25 that a HACCP program does exist, number two; number three, make
26 sure as they are currently doing and they're quite capable of doing,
27 that these records are done, these checks are made. In other words,

1 what is said in the program is actually being done and give that
2 inspector the opportunity to say I don't know if this thing is right or
3 not right. I've got some questions about this plan. I would like to
4 have it reviewed. And then have in your areas a team or a HACCP
5 expert -- you know -- that word's been thrown around a lot -- or a
6 HACCP coordinator or whatever that could then take a look at that
7 cause I'm not sure we're being fair to all the guys in the field here to
8 have them -- you know -- put a kind of stamp of approval on this
9 thing and I would rather that you let that guy circulate around so
10 everybody knows that sooner or later they can expect this guy in who
11 will really do a validation on the HACCP plan and, number two, allow
12 an inspector kind of the capability to say -- you know -- I'm not real
13 familiar with this thing, I'd like somebody else to step in here and
14 validate this.

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

24 MR. SMITH: We want to equip our people with our training in
25 order to be able to do what we're asking them to do and I think it was
26 very similar to what you just said what I said earlier -- that they are
27 able to recognize that at least a valid analysis -- hazard analysis has

1 been done and that critical limits have been put in place to control
2 those hazards and those type of activities. We do plan also -- we've
3 been talking the in-plant role -- we do plan also to have teams going
4 out and reviewing and doing in-depth validations of HACCP plans. But
5 we don't know the frequency of that would occur and I also said
6 earlier, I believe, that if an inspector does have a question on a
7 critical control point or any that they will be able to get to
8 supervision -- the area office -- and then from there their answers -
9 - their questions will be answered which will include sending out a
10 team to look at a plan or sending the plan in to have it looked at by
11 our experts in Science and Technology. So that is our plans.

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

23 MR. BILLY: Okay. I'm going to review my list. It's getting
24 longer. We've got Pete and then Dave Butler, Joe, Gerald, Dane,
25 another Joe. I don't know if that's the same Joe. Carole, Joe Pocius,
26 Jim, Marvin, Jim Hanks, Angie, Tony, and did I miss anyone? Steve
27 and Mike. Okay. All right, so Pete.

1 MR. PETERSON: My name is Pete Peterson. I'm associated with
2 the National Meat Canners Association and I also run the Bunker Hill
3 division of Castleberry Foods. We are meat canners. I concur with
4 Dave's statement that we've been in HACCP since 1986. I date far
5 back previous to that but after years of haggling with -- between the
6 Department and the industry we recognized that early in the 80's that
7 we had the potential of our consumers eating the most lethal
8 organism known to mankind -- botulism. And that wasn't detected by
9 looking at the exterior of the can cause it didn't cause any gas
10 formation in there. So we got and sat down together and developed
11 the canning regs which are twelve separate but interconnected
12 sections that completely meet the USDA's HACCP regulatory strategy.
13 We start with a definition. They get into containers and closures,
14 thermal processing, processing schedules, operations in the plant,
15 equipment and procedures for heat processing, processing and product
16 records, record review and maintenance, process deviations, finished
17 product inspection, personnel and training and a recall procedure. Our
18 product does not leave our plants until all of these sections are met
19 and reviewed. I would encourage all sides of this issue, including the
20 Department, to go back and read 9 C.F.R. Chapter 3, Part 318. And
21 Sub-parts G for meat and X for poultry. In addition to all of this,
22 annually, our industry conduct or put on several better processing
23 schools which are held at various universities around -- across the
24 country. I know that USDA sends their inspectors to these better
25 processing schools. We send our employees to these better programs.
26 The instructors in these schools are from academia, from the
27 industry, from Detroit associations, and it covers HACCP. In addition,

1 our companies on our staffs one or more process authorities so that
2 we can handle and verify our own deviations. Our records are
3 available to the plant inspector for review and are reviewed on a very
4 routine basis. And, again, I say our product doesn't leave our plant
5 until all of these control points have been met so you've got a
6 blueprint to work with. I think -- you know -- you're haggling over
7 how you're going to do this. Go back and read this blueprint. It will
8 give you an excellent road map to go down the HACCP road by.

9 MR. BILLY: Dave Butler.

10 MR. BUTLER: Thank you, Mr. Billy. I've got so many things I'd like
11 to address here but we've got a lot of top management here and -- you
12 know -- inspection has come a long way in the last twenty five years
13 and I'm an inspector from Missouri and I've been with them twenty
14 some years and -- you know -- I have a sympathy for them. Their
15 labor problem is hard to get. People just aren't like they used to be.
16 Now if these top management officials here today would send their
17 supervisors in the line here to this discussion I think it might be a
18 little bit different but when you're working in one of these meat and
19 poultry plants or whatever it might -- whatever type operation --
20 now your canning industry is a little bit different than your meat or
21 poultry or your raw product or your immediate cooked. Now, I've been
22 in so many plants and I can give you war stories here that just would
23 set you on fire and -- you know -- top management has good ideas on
24 what they want to do. These guys here probably do -- every one of
25 them. But when they go back and it starts to funnel down into the
26 chain of command down below it loses out. I mean there are people
27 just aren't following up on what they're supposed to do and it isn't

1 just in the meat industry. It's in any type of operation you see. We
2 don't have the good labor force like we used to. People don't pay
3 attention. Of course, the older I get I find that's with me. But -- you
4 know -- I've worked in plants for many years that's got high dollar
5 stainless steel equipment. You know -- they spent a lot of money.
6 And the object of this -- money's the name of the game and if you
7 don't run your operation to make money you're going to be out on the
8 street. You can't afford not to. You've got to work with your
9 inspector and veterinarian in the plant. Now, we've got so many
10 places that they'll write their own PQC program, TQC program and
11 approve it and they cannot follow it. Now top management has --
12 they say yes, we want to follow it. But when you follow down to the
13 plant supervisor, the manager, the assistant manager, and the people
14 that's doing the actual operation in the field, they're not doing it. I
15 can give you many cases of cooked product. They'll drag it out of the
16 smoke ovens before time's up because they got to get "x" amount of
17 product run and they can't do it. It's got to come out under
18 temperature form unless you're there to catch them. Records are so
19 easy to falsify. It's -- and you can't catch them.

20 Now, I think before you go too far on your HACCP -- you know --
21 I think anything you do to make the inspector's job easier that's great.
22 We appreciate it. When we go out here and start writing up these
23 programs if they follow them that's great but they're not all going to
24 do it. They promise you the moon and you go out here and start
25 implementing and checking on the plants, they're losing out. And we
26 have -- I'll just give you incidents and I can tell you -- --. I was
27 working in a plant and I won't tell you what type of an operation or

1 what the product is. I saw maggots crawling on the floor and they
2 had a long conveyor like this running product down the line. Now they
3 had a stuffer to blow meat up on a probably ten or fifteen twenty foot
4 ceiling. A couple days prior to that maggots is working in the product
5 up on the ceiling and after a while they ate it up and started falling
6 on the conveyor but their employees didn't catch this and the USDA
7 inspector did. We've got plants where we have metal problems --
8 metal contamination. They didn't want to stop their operations. We
9 had to force them to do it. We've got plants that run spoiled products
10 in the coolers -- you know -- and we stopped their operation. Again,
11 how are they going to police themselves? I mean this sounds great
12 today and if followed it would be great and a lot of plants will. I
13 mean not all plants -- but I think every top management has good
14 intentions but when you get down to the lower ranks and the working
15 force out there communication is a problem. We have so many
16 different nationalities working. They cannot speak English in these
17 plants and they're dealing with a food product. And really whenever -
18 - if it's an inspector -- if he started working on a product on the line
19 you forget about it being a food product. And it's also awful easy to
20 do. And I think that -- I think Alan up here touched on inspection --
21 on the training. I'm sure that -- you know -- a week's adequate
22 training is for most inspectors -- I mean we've been in so many
23 plants out there that the TQC people have had their problem of
24 management telling them to back off of their job and not be so strict.
25 You know -- they can't tie up the product. But you got to work this
26 out some way.

27 MR. TAYLOR: A couple of comments in response, Dave. The

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

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

1 follow it, I think, with this.

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

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

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

22 MR. POCIUS: That's what I was going to comment on if I could.
23 Thank you. I cut you off there Dane. Two things that I did want to
24 mention and one was that it seemed to me at this end of the table
25 that we hadn't really come to closure on what happens when you fail a
26 CCP and from what I heard from Caroline it was some least some
27 misunderstanding of how that works and I hope I clear it up and don't

1 up a bee's nest instead but when you fail a CCP, in fact, that may
2 result in a line stoppage. You're right. Because of the consequences
3 of failing a CCP and the health thing, that doesn't mean that the
4 HACCP program failed and I think that's what Bill was talking about
5 and there's a big difference. It doesn't mean that the program goes
6 through revalidation. It means that a corrective action has to be
7 taken. You also have to control that product and the product should be
8 evaluated by a process authority to find out how badly the
9 consequences of failing that critical limit are. Is it, in fact, failed to
10 the point of being an actual public health risk or can you release it or
11 can you rework it? Okay. I mean those things weren't -- I don't think
12 -- made very clear during the previous conversation.

13 There's one other thing I want to touch on as long as I have the
14 mike and that was the description of minimum CCP's and
15 identification of minimum CCP's. That may -- again, I'm with the
16 National Turkey Federation. In our industry we have large companies,
17 we have mid-size, we have small companies and the mid-size and
18 small companies have all pretty much said the same thing and we
19 can't forget them in this that they need some help here. They would
20 like to have some of these things identified but there's a difference
21 between identifying these things, putting them into guidelines, and
22 mandating them. We would all disagree very strongly if you were to
23 mandate them because then the purpose and the flexibility of HACCP
24 is defeated. On the other hand, if you were to put those into
25 guidelines and supply those guidelines to the industry they may help,
26 particularly the smaller companies get along, but one problem that I
27 have -- that we've seen with guidelines and I'll give an example --

1 the directives on basting poultry. There are examples that are given
2 in that directive that are interpreted in the field as the bible and
3 that's the problem with guidelines. Sometimes after time goes by
4 they're interpreted hard and fast rather than as suggestions so just to
5 keep in mind should you go that way as well.

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

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

23 MR. SMITH: I just want to follow up on the enforcement. To talk
24 about the CCP failure, one of the critical components of a HACCP plan
25 is to identify the corrective and preventive action when a CCP is not
26 met. What we are expecting is the plant -- if we had a cooking
27 failure, as we said there, and they rolled it into the cooler they would

1 then, as a follow up to that, to a disposition of that product would get
2 an analysis done probably from a processing authority to go back to
3 meet or equal or exceed what the critical limit was originally
4 established for. So if you had a cooking temperature established for a
5 5-D reduction of 015787 and a 7-D reduction of salmonella and the
6 product did not meet that then it would be the responsibility of the
7 plant to have that evaluated and determine how that critical limit can
8 be met before that product can go out. That is the expectation that
9 the plant will do that. If they do that, and this is a little different
10 for inspection but it's part of the culture shift -- if they do all that
11 and they determine either through either re-cooking or the cook that it
12 did receive was rigorous enough to meet the critical limit, that that
13 product can be shipped without FSIS's blessing of whether that can
14 take place or not. We will verify that corrective action through our
15 verification process such that we would expect then to see the
16 analysis by the processing authority that said that that did result in a
17 5-D and a 7-D kill and that the decision could be made to ship it. It's
18 a little different mind shift.

19 Now, if the plant does not do that then -- and we need to take
20 control of the product for failure then we have a systems failure. Not
21 only is the product retained but that process is suspended. And the
22 HACCP plan is invalid at that point because we have had a system
23 failure. So we need to understand that we have a responsibility to let
24 plants take corrective action when a limit is not met and as long as
25 they're doing that and we're verifying that then we have a system
26 that's working. However, as Mike was saying, if we have system
27 failure, then we are going to use our authorities which would be as

1 proposed -- suspension -- and we initiate the rules of practice of
2 what goes along with that towards withdrawal.

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

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

1 after four.

2 (A brief recess was taken)

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

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

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

25 One of the questions that occurred to Mike Taylor and myself at
26 the beginning of the break was whether -- you know -- there are
27 some groups that we haven't heard from yet in terms of this issue of

1 inspection under HACCP and the role of inspectors and that would be
2 particularly those people that represent the smaller plants. And so I
3 wanted to make sure that they were felt that these discussions were
4 covering their concerns. I know they raised some concerns in their
5 comments in this area. This was a particular area of emphasis so --
6 you know -- please be sure to grab a microphone and raise your
7 concerns or if they haven't been addressed or there's a particular
8 angle that you want covered that hasn't been addressed to date it's
9 real important for us to hear what your concerns are. So I just
10 wanted to make sure that that would happen to the extent it needs to.

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

25 Okay. The next person on my list is Gerald.

26 MR. LORGE: My name is Gerald Lorge. I'm an inspector with FSIS.
27 My biggest concern with HACCP is that if we're going to have an

1 opportunity to look at the product. We talk here about checking
2 establishments, documentations, standard operating procedures,
3 besides performing our PBIS tasks and the other numerous daily
4 papers that we have and it seems like we're just getting away from
5 what we are really sent there to do which is to look at the product.
6 And we're concerned that if this -- if HACCP is not turned into a
7 vehicle to start less than continuous inspection or carcass by carcass
8 inspection in the way where in something like in excess of nine
9 hundred inspectors short in personnel now and doubling and tripling
10 an assignments and barely can make the mandate -- -- every
11 assignment that we get and some of them don't get visited every day
12 and we just don't want to see HACCP as a way of justifying or
13 eliminating the continuous inspection and that's all I have to say.

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

26 MR. LORGE: I'm more or less talking about the additional burden
27 already put on the inspection staff by shortage of help and adding in

1 addition to that the HACCP concept with checking these tasks, the
2 paperwork management, and that type. We can't meet all these. We're
3 barely meeting our minimum requirements now. And is it really going
4 to help the system? Really all we're looking for is microbial testing
5 and checking for the invisible pathogen. We already have regulatory
6 enforcement in place in the progressive enforcement action and I
7 don't see the reason for adding all this other task when we really just
8 need the microbial testing.

9 MR. TAYLOR: Let me just make a comment on that. One of the
10 advantages that we see in HACCP is that it is a tool for focusing both
11 plant effort and inspection effort on the foods and the process they're
12 most critical for the safety of the product and as a framework for
13 both producing safe food and then providing inspectional oversight
14 for, say, food production processes, HACCP has that critical
15 advantage and it also by virtue of the record keeping aspect and the
16 systematic process control aspect has the advantage of really
17 expanding an inspector's ability to assess whether a plant is
18 operating under control with respect to those critical safety factors.
19 But HACCP and the oversight of HACCP in terms of inspecting records
20 and so forth is not a substitute for in-plant observations of product,
21 in-plant observations of activities being carried out by the company
22 in the plant, and certainly not only not a replacement for microbial
23 testing but I think we envision in a regime in which we are moving
24 towards performance standards for harmful bacteria on product that
25 we don't critically have there will be no doubt an enhancement of the
26 role of product sampling and microbial testing by FSIS as part of its
27 oversight functions. So, again, I think it is a mistake in

1 understanding what HACCP is about to think of it as a substitute for
2 in-plant inspection. It is a framework for very fundamentally
3 changing but enhancing, not changing and diminishing, changing and
4 enhancing the contribution that each inspector can make to insuring
5 the safety of the product. So it's not by design a substitute for it.
6 It's an enhancement of that in-plant inspection role and definitely not
7 a substitute for looking at product. It's just that we've got to focus
8 our efforts, just as the plant has to focus our efforts, on the most
9 critical foods in the process from a food safety standpoint. That's
10 the organizing power of HACCP, if you will, from an inspection
11 standpoint and that's why it should serve as an enhancement.

12 MR. JAN: Lee Jan, National Association of State Meat and Food
13 Inspection Directors. Regarding Inspector Lorge's comments about
14 concerns with HACCP taking away or going to where an inspector
15 doesn't have to be in a plant every day, I think that HACCP is the
16 system that will allow that and with today's shrinking budgets and
17 hopefully growing industry if you mandate daily inspection and HACCP
18 as well you're going to have to violate or not meet your own
19 requirements for daily inspection. You're going to have to get away
20 from daily inspection. And Mr. Allen asked that or suggested that
21 inspection be a set -- a new set of eyes or third set of eyes because
22 their people tend to get barn blind to use his terminology because
23 they see it every day. If we have an inspector in the plant every day
24 they can get just as barn blind so I think you can have a better
25 inspection with the HACCP that is a functioning HACCP, it's a program
26 of the plant. We do have those verification tests and record
27 verifications that prove or verify that the HACCP is working but we

1 cannot continue to say or continue to go with -- we have to be in the
2 plants every day. You're already not doing that. The rules are that you
3 have to be in there every day but that's not happening. I've heard that
4 said several times today by the inspectors that they can't be in the
5 plants every day so we need to get away and accept that and move on
6 to let HACCP take its role and as far as the small plants as well as
7 large plants need to be in this mode to go to HACCP. I do want to
8 bring out that the small plants will need some extra help or be
9 allowed to get some kind of help where they don't have a quality
10 control staff. Their only quality control staff is the manager or the
11 plant owner and I think there's a role for state agencies, whether they
12 be health departments or like in our case, a state meat and poultry
13 inspection program, that can be there to give them not a helping hand
14 but be there to kind of help guide them to developing their own HACCP
15 plans. And I think from a broad picture those big plants -- we've
16 heard from Excell and the Cannery and Hormel -- a lot of them have
17 HACCP plans now. They all belong to our organizations. If those
18 organizations would get together or individual organizations work
19 with the experts at FSIS to develop HACCP plans guidelines -- not
20 HACCP plans but HACCP plan guidelines that have input from both the
21 experience of industry and the expertise of inspection or regulatory
22 expertise and come up with plans that can be easily accepted by
23 regulatory, even though they're primarily developed by the industry.
24 And I think that would be a great help to develop those type of
25 guidelines for small plants. And I think just because they're small
26 doesn't mean they can't go HACCP. I think they should go HACCP. They
27 just need those little extra help. Thank you.

1 MR. BILLY: Dane?

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

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

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

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

21 There was also discussion of the role of generic HACCP plans
22 and Lee said it very well. There is a role and Mr. Prucha said it very
23 well as well. There is a role for generics. I think by and large the
24 industry wants to have the latitude to develop its own HACCP plans
25 which reflect the particular needs of a product and plant and line.
26 Generics can serve well as models for use in training and can be
27 adapted by smaller operations who don't have the capabilities of

1 conducting hazard analyses but these should not become standards
2 just because they're developed by the agency and put on the table by
3 the agency. Every company's HACCP plan should be viewed in the
4 validation process on its own merits. There was also talk about the
5 shift that needs to take place and it has been said but I want to
6 clarify that the shift is not only in the agency. There's shift needed
7 within the industry. We here in Washington tend to go quickly from
8 the objectives and we get lost in the details. Keep your eyes on the
9 objectives. The objective of HACCP is to come up with a safety
10 management plan which is then translated very quickly to the people
11 who have the most direct control over the safety of the foods we
12 produce and that's the people on the line -- the operating people. That
13 is done and you've heard many times from several voices here of
14 people with HACCP experience in plant. It's done through cooperation.
15 It's done through training. And the same dynamics must be embraced
16 by the agency. It's got to get down to the field and operations level or
17 we're not going to get the benefit that we all strive for with this
18 particular system. Is it easy? No. If it were easy we wouldn't have
19 this room full of people here discussing it. Is it going to take time,
20 is it going to take a lot of discussion? Yes. It's not time to give it up
21 and just go to finished product testing as the criteria by which we'll
22 judge the safety of the product. And Mr. Taylor said very well that
23 what we hope to accomplish in HACCP is to enhance the safety of the
24 foods by having better control over the operations. If we inspect
25 products, if we test products, we know that the product we test has a
26 certain characteristic. That may or may not translate to that same
27 characteristic in every unit of product. If we do our homework

1 correctly and put together good HACCP plans underlying the operative
2 word HACCP plans we will have greater confidence in every unit of
3 product that comes out of production line and that is the ultimate
4 objective is to gain that greater confidence in every unit produced.
5 Thank you, Mr. Chairman.

6 MR. BILLY: Joe Pembroke.

7 MR. PEMBROKE: Thank you, Mr. Chairman. I'd just like to expand
8 on a few comments that we've been hearing around this table. First
9 of all, I'd like to say that I've probably served the Department of
10 Agriculture for seven and a half years in the regulatory division and
11 while I was there I was assisting and drafting many regulations
12 promulgated under the Meat and Inspection Act and Poultry Product
13 Inspection Act and, in fact, I went toe to toe with many of the
14 attorneys in this room withdrawing inspection for some of the plants.
15 I now work for a large food company in the United States which has
16 divisions which include some of the largest processing meat and
17 pizza companies and I'm also here as a delegate for AFIE which is the
18 American Frozen Food Institute. It's a national trade organization
19 representing frozen food processors, suppliers, and marketers. There
20 is a 560 member company and accounts for over ninety percent of the
21 frozen food products in production in the United States. I was honored
22 to serve here and I have the utmost respect for both the compliance
23 and the inspection staff. However, we need to see why we're here in
24 HACCP. It's a distinction that I think we are not making between
25 slaughter and processing. And HACCP gives us the ability to
26 recognize this distinction and to allocate the agency's resources. I
27 agree with the agency that no formal prior approval acceptance of an

1 establishment's HACCP plan by FSIS is needed. In fact, when I look at
2 some of our Tombstone Pizza Companies' inspectors are only in our
3 plant on average -- you know -- two or three hours a day. I don't
4 think the likelihood of producing an unwholesome product in the five
5 or ten hours that the inspector isn't in the plant there is any greater.
6 We have PQC, TQC programs that are precursors to HACCP and I think
7 Dale and other people said that when you evaluate a HACCP plan it's a
8 process over time. You can't just go in and check it off and say this
9 piece of paper proves that it's working. You have to look at it over
10 time. HACCP plans are dynamic documents and I think we all agree
11 that they're subject to modification and improvements. I think if we
12 require a prior approval or requirement for such an approval it would
13 inhibit or slow down this process and prevent industry from coming
14 up with continual improvement.

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

25 MR. BILLY: Carol.

26 MS. FOREMAN: Thank you. It's clear that all of our -- this is
27 Carol Tucker Foreman again. It's clear that Joe, and Dane, and I all

1 flipped our flags out at about the same time. I put mine out because
2 Alan Oser was talking about the problem being that HACCP is a non-
3 standard procedure by its nature and it's hard to impose a
4 standardized system on it and, Bill, I wanted to try to tee through
5 something with you.

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

11 MR. SMITH: Yes.

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

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

23 MR. SMITH: We would envision that that would be part of plant
24 verification activity. That is one way of verifying the effectiveness
25 of your HACCP plan would be testing to see if there's a kill step that
26 the product is pathogen free. So that's one possibility of doing that,
27 yes.

1 MS. FOREMAN: Is there any other way to do that?

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

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

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

1 testing is something that has occurred as we've seen HACCP used for
2 control of various processes and it's something that we can expect
3 would be a part of processes that would be coming under HACCP at
4 this point.

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

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

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

19 UNIDENTIFIED VOICE: Could you restate your question?

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

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

1 there is a -- a -- the kill step is effective.

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

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

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

26 MR. TAYLOR: Let me just make an observation again, sort of
27 indication of where our current thinking is. I actually think when you

1 -- when you see the approach that we're considering in adopting
2 performance standards as an option for cooked product. In the
3 backgrounder that we handed out today gives you a brief description
4 of that planned proposal you'll see what I mean about our current
5 thinking. But we have to distinguish between the role that testing
6 might play in the validation of a -- of a plan or a process with --
7 which is a kill step plan or process and the testing that might be
8 required and verification of that on an on-going basis and operation.
9 And I think it's -- well, theoretically there may be some -- I suppose
10 some plans or some set of plans or controls that are so thoroughly
11 tested and established in the literature that there -- you can
12 prophesize perhaps -- theorize that you wouldn't in a particular plant
13 setting need to do microbial testing to validate in that plant. It's
14 very hard to imagine that you would -- you could appropriately
15 validate the operation of a kill step process in a particular plant
16 without some testing as part of that validation.

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

1 definitely a role for microbial testing.

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

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

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

21 MR. PETERSON: Which?

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

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

27 MS. FOREMAN: That's exactly what I wanted to know. Great.

1 MR. PETERSON: Well, she didn't ask me about micro that time.
2 She asked me if we looked at the problem.

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

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

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

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

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

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

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

20 MS. SIEMENS: This is Angie Siemens with Oscar Meyer. In
21 actuality we do product testing. What we do is equipment testing
22 relative to sanitation, pre-op, operational equipment testing, we do
23 shelf life samples where we run samples but we do not do pathogen
24 testing. Let me back it up and say pathogen testing on our product to
25 insure our products have done. But we are very committed to
26 integrated validity relative to understanding some of the basics in
27 the science transfer that has come out from the studies showing

1 lethality curves and our time and temperatures are highly regulated.
2 We have HACCP plans in every one of our processes now that are
3 based on the science dealing with a lot of the integrated lethality
4 premise and the science based around what a lot of the roast beef
5 regulations were determined around. But we are not doing consistent
6 pathogen product testing to verify our programs. We feel that using
7 the HACCP plans, and Dane alluded to this before, that we are
8 comfortable that we have validated the current plans that we have
9 and continue to work with those plans and are not, unless there's a
10 deviation that comes up that was mentioned before, we're not going
11 to go back and do a consistent product testing.

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

13 MS. SIEMENS: We've not done product pathogen testing on
14 product testing. We've used our experience based on what we have
15 seen in the past of cooking temperatures plus regulatory cooking
16 temperatures because there are regulations in place for final product
17 temperatures that have assured safety been based on a long history of
18 --

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

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

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

27 MS. MACKLOW: Probably not in them, maybe on them, because

1 the issue becomes one of recontamination because of different steps
2 -- -- to make --

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

5 MS. SIEMENS: The critical limits that we established within our
6 plant. Critical limits relative to temperature. Let me tie in with
7 that because that's what we're dealing with -- basically the final --
8 and I have to be careful to keep a job when I get home on some things
9 -- but critical limits are based on -- our poultry products, of course,
10 you've got the 155 and 160 mandated in the regulations. That is a
11 critical limit over time the government has established in terms of
12 being a final processed limit. We actually cook to higher
13 temperatures, not for safety reasons but for quality reasons. So not
14 only have we built in a factor, and I think many processors around
15 this room would say that we are not cooking probably to the absolute
16 minimum of many of the regulations which have already been
17 determined to have safety factors in them, we are cooking to higher
18 temperatures for many quality reasons. And it depends. Not every hot
19 dog is processed exactly the same and we've not got the same end
20 point temperature nor humidity, etc. in all those factors -- time and
21 temperature, humidity that go into those for each and every process
22 that we have. Because we've gone through and we're comfortable, not
23 only with the safety of the product, but we also have to examine in
24 our situation the quality of the product as well. And, again, the thing
25 that is -- we're just not starting to cook hot dogs. We may be just
26 instituting a HACCP program which is a different way of examining
27 the safety but we've been producing safe products for decades and we

1 base ourselves off of that history on the temperatures that we
2 develop and that's where I think we get into, based on the history of
3 it, we feel comfortable. We don't have to validate over and over again
4 that our processes are safe. It's a continuing process. It's been a
5 learning experience, etc.

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

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

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

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

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

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

17 MR. OLSON: Excuse me. I'm Phillip Olson. I'm from Olson, Frank,
18 and Weda, counsel for the National Meat Association. Seems to me
19 there are two different hazards here. One hazard is the risk that
20 there will be salmonella in a cooked sausage when it comes out of the
21 cook house and what I'm hearing people say here is that if the time
22 and temperature requirements are met it's like meeting the time and
23 temperature requirements on something at home. That there's certain
24 levels in which there's a built-in safety factor. There's another -- so
25 that's one thing in a plan. Do you -- is that something -- what is your
26 control for that and it may well be to show that you cook to a certain
27 temperature for a certain time.

1 Now, the other substance you're mentioning -- the other
2 bacteria is listeria. Listeria is a re-contamination and so there I
3 think you'll find companies in their HACCP plans will address that
4 differently, either by sanitation measures or environmental sampling,
5 but that's not in the product so it comes down to HACCP plans
6 meeting the individual identified hazards and then have appropriate
7 response.

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

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

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

16 MR. LOCHNER: What we do on occasion -- there's different
17 philosophies. This is Jim Lochner of AVP. Some people do and some
18 people don't. Now, depends upon the history and the confidence you
19 have with your history and I do believe a long time ago that all
20 processed meat manufacturers before the legal liability issues in a
21 classification of adulterance have built up histories on time
22 temperatures with various processes. Now, personally, I do take
23 occasional samples for salmonella on cooked items. And I hold that
24 lot, don't release it until I have a confirmed negative result. So, do
25 that on a routine, not every day, not every batch, but on a periodic
26 basis it comes up. Therefore, I have confidence that the HACCP plan -
27 - to me, that's just a built-in check. Now you can do that. That's your

1 option and I don't know if we're after on this set of questions should
2 that be -- I think your question, Carol, should that be a matter of
3 routine or should that be an assumed, if I'm asking your question
4 right.

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

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

13 MS. FOREMAN: Right.

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

18 MS. FOREMAN: That's tomorrow, Jim.

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

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

23 MR. BILLY: Dane?

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

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

26 MR. SMITH: On cooked product we are sampling today for
27 salmonella, listeria, and E. Coli 015787, not in cooked products, but

1 in the raw. Those sampling plans or programs will still be in effect.
2 And they would be a check on those programs.

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

8 MR. BILLY: Dane?

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

22 Angie's process as well as any other process that you set up on
23 that basis starts with microbiological testing. It's there. It's kind of
24 like that commercial for spaghetti sauce. It's in there. Doesn't mean
25 you have to test every lot but it starts with microbiological testing
26 of a scientific nature to find out what time and temperature it takes
27 to kill the target population of bugs. That's pathogen, that's spoilage

1 organisms, that's things that limits your shelf life and we take all of
2 that as we have done over and over in cooked sausages and say, that's
3 our target. We need to achieve "x" many minutes at "y" temperature to
4 have faith that this product is going to be safe when it comes out of
5 the cooker. Then we take that to the plant and we say, okay, here is
6 the cooked device. What are the variabilities in that cooker? Can we
7 count on every 2,000 pounds, every pound of that 2,000 pound batch
8 that comes out of that cooker receiving at least that cook as a
9 minimum and how do we set it up and how do we validate that? If it's
10 a smokehouse you want to make sure the smokehouse has been
11 balanced with good temperature readings in the smokehouse and we
12 know how long it has to be on at what temperature to achieve a
13 minimum internal temperature in every sausage that's in that
14 smokehouse. That, to me, is HACCP. Now you've given me the
15 background data on setting up a critical control point and your
16 critical limits. I can go in and look at those records. I develop a
17 great deal more faith in every pound of sausage that has come out of
18 that operation than I will if we're just relying on micro testing. Does
19 that mean we never do micro testing? No. Didn't say that. If a
20 company so chooses or there is variability in the process then
21 possibly there should be some verification testing of a
22 microbiological nature but it depends on how well established the
23 process is and what sources of variability are. But to set up a
24 mandatory program for cooked products to say that we have to test, if
25 the government wishes to do so, fine, but to force companies to do so
26 I think is not consistent with what we're trying to do. Validated
27 processes is what we're after and what you have to do to validate

1 those processes and come up with that kind of warm, fuzzy feeling on
2 all product that comes out of there is what we're after here. Thank
3 you.

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

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

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

23 MR. OSER: No. I'm talking about cooked. I'm sorry. If you look at
24 the cooked salmonella figures on fresh products like hot dogs, they're
25 all zeros. I think they've got maybe one in less ten thousand. Does
26 that mean there's no cross contamination going on in the packing
27 industry? Probably not. Because if you look at the figures for

1 listeria you'll find some. You'll find some. Listeria doesn't
2 necessarily mean cross-contamination. But, if you look at what Oscar
3 Meyer's doing it was found early on when we got into this listeria
4 thing that if you're going to find listeria on the product you're going
5 to find it in the environment much, much, much more frequently than
6 you'll find them on the product. If you take a bad -- what would be
7 considered by industry standards a bad acting plant that would have a
8 five percent rate of listeria contamination that's one sample out of
9 twenty taken on a given day. So you could take nineteen samples, fine
10 enough, and it doesn't really mean anything. I think the average
11 listeria -- I'm pulling figures out of my head -- it's probably closer
12 right now to between one and two percent -- something like that --
13 so to find out if you really have control of listeria you would have to
14 take ninety eight hot dog samples or a hundred probably and if you
15 found two you know, okay, we're about as good as the current
16 technology. It doesn't really tell you a whole lot. On the other hand,
17 environmental sampling was found very early on that the organism
18 would turn up in an environmental sampling routine much quicker than
19 it would turn up on the product.

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

25 MS. FOREMAN: On listeria.

26 MR. OSER: Uh-hmm. On listeria.

27 MS. FOREMAN: But not on salmonella.

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

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

20 #5 MS. FOREMAN: Thank you.

21 MR. POCIUS: Joe Pocius with the National Turkey Federation.
22 Just so -- in another life way back when I worked for a company who
23 did canning. In fact, we did re-tort pouches so I want to reiterate
24 what Dane was saying as how you describe the parameters or critical
25 limits for critical control points and, Carol, I think that's what you
26 were asking but you went further and asked, suppose you see a system
27 that you're not familiar with, it doesn't look like anybody else's, how

1 can you verify that or validate it? In our case, that would be like
2 changing the formula in a pouch. We haven't seen that product before.
3 We have to revalidate. I would expect in the canning industry you do
4 inoculated pack study and once you've done that and once you know if
5 what your time temperature parameters are -- I'm trying not to get
6 into Z and F values here -- but once you know what your time
7 temperature parameters are that's it. As long as you meet those you
8 know you have a kill step. That's the information I would expect for
9 anyone who has a HACCP program that doesn't look very normal. When
10 they describe or they go through a hazard analysis and they say, well,
11 at this point in our process 132 degrees fahrenheit will work well
12 they have to have data to support that. After that, you don't have to
13 take micro samples as long as they meet that time temperature
14 parameter because you know it's a valid kill.

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

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

18 MR. POCIUS: You implied.

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

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

24 MR. BILLY: I have sixteen names. And if my watch is right we've
25 got about sixteen minutes. I'd like to -- I don't want to rush this
26 discussion. We can continue it if we choose to or keep going after
27 five thirty. But I'd like to encourage people to keep their comments

1 short, if that's possible, and see how far we can go through this --
2 through this list.

3 Next person I have is Marvin.

4 MR. LEWIS: Lewis. I'm a USDA inspector also. I would like
5 several gentleman related their credentials. The gentleman from
6 Hormel, I believe, who has left. I have sixty two years. Twenty years
7 -- it's farm to table. I was born on a prairie farm in Missouri for the
8 twenty years; eight years in inspected industry; and thirty four years
9 as a federal inspector. All as a lowly inspector in charge thirty of
10 those years. I was involved in the first TQC. In fact, the first TQC
11 plant in the nation and three of the largest, which two are Oscar
12 Meyer. One was closed. But, anyway, for ten years as an inspector in
13 charge. I monitored micro programs, pre-op swabs, operation swabs.
14 At another company, Eckrich, I believe it was, I did surface counts
15 and core samples on microbiology. Of course if was quantitative
16 analysis and not qualitative -- not identifying the particular bacteria
17 -- but I've been involved with all these programs. We're talking about
18 TQC basically with the exception of adding of the bac T sampling and
19 the carcass chilling. I see HACCP as nothing but mandatory TQC. It's
20 a different critical control points. TQC you had to identify all the
21 critical control points to comply with the current regulations and we
22 as inspectors in charge wrote those plans on how to monitor those, do
23 the verification. I think validation verification is synonymous and
24 meaning evaluating a lot of paper. But in that time there is
25 breakdowns in the system. She's right. They might process hot dogs
26 at a 178 degrees in the third stage of the continuous system. But
27 once, I believe, there was a breakdown -- a mechanical breakdown.

1 These things happen. Some fans kicked up. Six minutes or seven
2 minutes of under-processed products. They run twenty hours a day
3 and about six continuous systems. And they were traced, they were
4 found by old fashioned -- -- inspection. Some consumer realized they
5 looked undercooked and watered and they were all recalled. I
6 monitored the recall of the product and then I've got out to anyone but
7 as a mechanical breakdown. These fans didn't kick back on
8 automatically and so they had to be wired. But that just meant we
9 know about the bac T and the finished product testing to get 178
10 degrees you don't have to worry about salmonella and listeria.

11 But, anyway, I would like to defend the inspector in charge. All
12 you people from the corporation, from the agency, I'm sure you have a
13 vast lot of experience. They're talking about day one. Mr. Taylor, I
14 think he's been in about a year, maybe three sixty. Me, it's day
15 fourteen thousand something, I believe. And I've been involved with
16 all these programs in the past and nothing is fail safe. I have
17 condemned probably over a million pounds of product after it was
18 past these systems. With all the paper involved, and you can get
19 covered up with paperwork. but I think we reduce it to the single
20 common denominator we're talking about -- inspectors' training. I
21 have inspected 500 companies probably in the thirty four years from
22 Illinois to California. Most as inspector in charge. I've dealt with
23 corporate people at all levels. Five plant managers in the largest
24 plants are also corporate vice presidents and many other big
25 companies and things happen but the inspector is no dummy. I think
26 Dr. Prucha and the other gentleman, Alan, had a problem with the
27 inspectors not wanting a uniformly interpretation but the inspector's

1 capable of learning such. It's really very simple. You don't have to be
2 a bacteriologist to have a four year degree. I monitored bacteria
3 program. I can observe the manufactured cultures, the swabbing, the
4 incubation and the counting of colonies as well as anyone. And to say
5 we're not capable of science-based and you're going to allow these
6 people in the HACCP program to take three days at a seminar to be a
7 qualified process and authority. Well, I think that we're over
8 qualified if that's what these people need. But I have no problem
9 dealing with any corporate people in my career as well as your
10 illustrious consultants.

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

12 MR. LEWIS: Okay. I'm done.

13 MR. BILLY: Thanks. Jim? Jim Hankes?

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

21 There's a lot of us small companies out there. I'm sure as Mr.
22 Billy and staff found out when we got to Kansas City a few months
23 ago and there's a lot of concerns out there. I think one thing maybe
24 the Department really needs to do is to beef up its communication
25 with the small processors. The small processor lack the staffing, the
26 people that have the knowledge about HACCP and HACCP controlled
27 programs. And we rely on the government who is the regulating

1 agency for this information. To get this information out to all the
2 small plants across the country -- you know -- I know it would be a
3 major undertaking but we're going to get copies of the regulations
4 when they're final and I think a book or some type of handbook with
5 guidelines to start to give a lot of these processors and people an
6 idea of what is coming down the pike is essential. There's a lot of
7 unrest among the small plants out in our state and I know in other
8 states. There's several of them that are looking at different options.
9 Some of the options are dropping inspection completely which I
10 personally feel is a step or maybe ten or twenty steps backwards into
11 the dark ages but these are things people are considering. Other
12 things are going custom exempt and doing away with the inspection
13 that way. There's even been talk about possibility of dropping state
14 programs and going federal where the federal custom exempt is more
15 lax, without regulation. There's talk about going and dropping
16 inspection and going to retail and relying on public health where in
17 some counties, even in the State of Illinois, there's some counties
18 that don't even have public health departments and then there's also
19 talk about, well, I know for a fact that there's people that aren't
20 doing expansion currently, they're not doing any upgrading of their
21 facilities, they're kind of in a holding pattern right now just doing
22 what's minimum, what's required of them till they can wait and see
23 exactly what the mega regs are going to produce. And then I would
24 imagine that once there is a final rule published some of these people
25 would be making decision probably to retire after whatever given
26 length of time they're required to implement the program. I know
27 people are putting the equipment purchases on hold. However, there

1 is obviously a group of us that are a little more aggressive. We're
2 young enough, we've got kids we want to send to college, we want to
3 keep making a living, we serve our communities, we provide
4 employment to our small towns, and we think that we're a viable part
5 of our communities and for these reasons we want to learn as much
6 as we can about HACCP and fortunately or unfortunately it's my job to
7 go back to our state and our association and get some of this
8 information back to our people and let them know what's going on.
9 There's a lot of people sitting in here from big companies, a lot of
10 inspectors. There's a lot of people here that necessarily don't get in
11 there and probably like myself and get their hands dirty and neither
12 work the kill floor, sausage making, processing, whatever needs to be
13 done. And I think it's important that we look at HACCP. We have
14 implemented several things in our plant which are very beneficial to
15 us and as we learn more about it we're changing our ways and we
16 want to get this information back to the small plants. The small
17 plants are kind of eagerly awaiting to see what's happening. Just in
18 defense of maybe the lack of attendance of this conference from
19 small plants it's difficult to get away. We found out about a week ago
20 when the meetings were going to be held, etc. And for a small plant
21 to take one or two people out of their facility to get away for three
22 days -- four days traveling time -- whatever it takes -- plus the cost
23 of coming out, it's a big job. So hopefully through our associations,
24 through our national associations, state associations, and we can help
25 the Department relay this information back. But I think it is
26 important.

27 I guess an example I'd like to give real quickly here. There's

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

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

24 MR. BILLY: Thank you. There's a session tomorrow on the role of
25 -- FSIS role of facilitating development of HACCP plans. You're going
26 to hear about some specific concrete plans for providing some of that
27 type of information you're talking about so that will come up

1 tomorrow so you'll hear more about that. You will be here, right?

2 MR. HINKES: You bet.

3 MR. BILLY: All right. Tony?

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

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

1 MR. DUGUAY: Thank you.

2 MR. BILLY: Steve?

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

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

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

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

26 MR. TAYLOR: No. We have a statutory mandate to do that. It's
27 achieving objectives, some of which may be addressed by HACCP but

1 others of which are not addressed by HACCP that have to do with
2 wholesomeness and other non-safety defects that we're responsible
3 for addressing. I think the issue we're looking at with respect to
4 carcass by carcass and certainly the top to bottom review has
5 examined -- you know -- various possibilities is not whether we
6 maintain the carcass by carcass but are there ways to improve the
7 use of our resources in carrying that out. Perhaps with HACCP as part
8 of the framework that might permit us to make a better use of our
9 resources so there certainly are issues about how we do carcass by
10 carcass but not whether we do it.

11 MR. BILLY: Steve? No, Mike.

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

18 One thing I would like to digress a little bit and say that in the
19 interim we should end up because sanitation is the major building
20 block of good program for anybody and through my twenty eight years
21 and being at just about every inspection job in this agency and this
22 isn't scientific but it comes from being on reviews and also in all of
23 these plants, I would say that I think we have records that show that
24 between five and fifteen percent of the plants out there have an
25 inspection and a plant failure when we look at serious deficiencies
26 and pest control and sanitation. And before we implement HACCP I
27 think we already have the authority to get these plants to a place that

1 they need to be cleaned up and I think that's one of the interim steps
2 we need to take cause a HACCP program will not work if the
3 sanitation program is not working. Thank you.

4 MR. BILLY: Ron? Patrick?

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

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

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

20 First, in terms of within your ability to control. I know that
21 these hearings were scheduled with short notice and that the agenda
22 was developed over a relatively brief period of time and that some of
23 the commitments that the Department had made in preparation for
24 these meetings would have required certain steps within that brief
25 period of time. The one that I'm specifically referring to is the
26 commitment to prepare in advance the documentation summarizing
27 the issues for discussion today, but more importantly, the agency's

1 current thinking. And if the lawyers from the General Counsel Office
2 were here I'm sure they would point out that you have technically
3 complied with that commitment as of late yesterday afternoon and,
4 again, for tomorrow's session as of late this afternoon. But I think if
5 you reflect back on the direction of the discussion that unfolded here
6 today, at least it was my own observation that as the hours passed
7 the focus became a little bit more precise. And I also believe that
8 the discussion became more substantive and I think more beneficial.
9 I would hope that you found it to be such. And it seems to me that to
10 the extent the agency is able to get those papers out in a more timely
11 way to the extent that they can contain as detailed and substantive an
12 analysis, not only the issues for discussion, but more importantly
13 your current thinking, I think we would find that every hour from nine
14 o'clock on is more beneficial and substantive than maybe the first
15 few hours were here this morning. In that regard I do want to
16 acknowledge that the Acting Under Secretary did throughout the
17 discussion interject current thinking on the part of the Department
18 that I believe was helpful as the discussion went forward but I
19 believe it would be more helpful if we had that current thinking in
20 writing in a more timely way.

21 To the item that is not directly within your control but
22 hopefully within your sphere of influence. I did have occasion to talk
23 with the Secretary's counsel, Kim Shnor, who has been with us
24 through most of the day about this earlier in the day. It was our
25 expectation, and I believe a reasonable one, that this discussion,
26 while I think is very substantive and meritorious today, was a
27 discussion that really was requested by or at least promised by the

1 Secretary to include him and that was clearly our expectation, not
2 only for today's session but for the other five sessions that are
3 planned, and in his absence, as he told us on a variety of occasions in
4 preparation for these meetings, he would have the Deputy Secretary,
5 Secretary Rominger in attendance, and, indeed, the Secretary did
6 come by later in the day and, indeed, the Secretary was here earlier in
7 the day, but there were seven hours of very good and worthwhile
8 discussion in between and I understand the demands of a schedule,
9 particularly the schedule of a cabinet official. As an administrator I
10 had a busy schedule and I was just an administrator here. So I
11 understand fully the demands and also occasionally the unexpected
12 conflicts that arise. But I would hope that the conflict that arose
13 today was an aberration in the sense that he does fully intend to
14 participate in future sessions or to have the Deputy Secretary present
15 and participating in future sessions because it's out belief that that
16 is truly what is going to result in a more workable and more
17 comprehensive and more effective regulation involving HACCP. So if
18 you could convey that to him and I will attempt to convey that
19 directly to him later today.

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

1 issues that we're addressing so I hope that will be helpful to you.

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

4 Alan? Bill?

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

11 MR. TAYLOR: We have a statutory mandate for a USDA inspector
12 to examine carcass by carcass, bird by bird and we intend to continue
13 to carry that out. That mandate is not prescriptive with respect to
14 the manner in which we conduct that inspection and we have a certain
15 manner of doing it that has developed over the years as you know and
16 have a lot of experience and expertise about. As I mentioned -- you
17 know -- in response to Steve's question, in the midst of our effort to
18 insure that we are making the best use of the resources we have
19 currently on board to improve food safety we have asked the top to
20 bottom review team that's looking at in-plant inspection roles to
21 consider whether there are alternatives to the current mode of
22 carcass by carcass inspection that would enable the agency to make
23 better use of its current resource and so certainly one question that
24 that group asked and did some analysis and laid out some options and,
25 again, you're probably familiar with them, one possibility that is
26 addressed is the possibility of having some of the tasks currently
27 performed by our inspectors be taken over by plant employees. Not to

1 totally replace the USDA inspector engaged in carcass by carcass
2 inspection but to delegate, in effect, some of the tasks currently
3 being performed and making the plant responsibility subject to
4 accountability and inspectional oversight by us. So there are host of
5 options and possibilities and so the question we're addressing is are
6 there alternative ways to carry out that mandate so that we would be
7 able to, again, make better use of that inspectional resource. For
8 example, to perform HACCP verification tasks, sampling, microbial
9 sampling tasks, other in-plant inspectional roles as well as roles
10 outside the plant. But the motivation to do that is to make better use
11 of that resource, not to cut that resource. And we've been very
12 explicit publicly, quite frankly, that -- you know -- unless we do
13 insure we're making the best possible use of every inspector we can't
14 achieve our food safety goals as fully as we'd like to and we will have
15 a very difficult time in this budget environment maintaining the
16 resource we have so with those motivations we're looking at how to
17 do it, not whether to do it.

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

20 MR. TAYLOR: Less than?

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

23 MR. TAYLOR: Again, I -- I mean first of all we currently have
24 adequate resource to do that. We're working hard on the current --
25 you know -- budget process for next year. You know -- we're
26 optimistic about having resource to do that and I don't frankly think
27 that Congress -- just my personal speculation -- Congress is

1 supportive of us maintaining an adequate -- I hope in the end will be
2 successful in maintaining an adequate resource to do that. That is
3 our absolute commitment in the Department is to pursue and obtain
4 the resources we need to do that job. Congress ultimately makes that
5 decision. But we're in pursuit of the resources we need to do that job.

6 MR. HARRISON: Thank you.

7 MR. BILLY: Okay. Rebecca?

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

20 There's -- I'm taking notes here. Cutting it down. Okay. There's
21 been a lot of referral as this -- the inspection, industry, HACCP,
22 being referred to as highway -- automobiles -- and the patrol
23 officers have advanced technology. They have radar, laser, which
24 caught me, even -- you know -- photography. There are lawbreakers
25 but that doesn't necessarily make them bad people. They're only
26 human beings. And no matter how many facets of checking if there's
27 no enforcers the technology alone will not work. We've got to blend

1 the two of them together. HACCP does have to enhance what we have.
2 And I think if you work the two of them together and because we feel
3 that industry maybe needs to be patrolled -- you know -- that doesn't
4 make you bad people either.

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

13 MR. BILLY: Joe?

14 MR. MAAS: I'll keep it brief. I'm a small processor. Back when
15 you said that somewhere along the lines someone along with my
16 colleague from -- I guess from Illinois down there -- my name is Joe
17 Maas. I own a meat processing plant in Cincinnati -- JTM Provisions.
18 I just wanted to say a couple of things real quick. I wanted to point
19 out the one thing, at least in my case and in companies my size, my
20 salary is paid by the consumer. There's just no way out of that. I do
21 not get any income from anyone but the consumer. On occasion I hear
22 people say -- you know -- that hey, we got to take responsibility for
23 the safety of the products and not let it be the role of the USDA's.
24 Well, I can tell you in my plant I carry -- I carry the responsibility
25 for every pound of product that leaves that plant. The USDA carries
26 none of the responsibility. If someone were to be harmed by
27 something that I sell it's not the USDA's problem. It's just flat plain

1 mine. I would certainly lose everything I worked for my entire life. I
2 would leave it go at that but if HACCP is something that is going to
3 be decided that is something that I have to do then I'll do it but I'm
4 perfectly comfortable with the system that I have in place in my
5 plant. I personally, myself, walk the floor every day. I own the
6 company with my three brothers. One of the three of us are there
7 every day walking the floor, making sure everything's going okay. I
8 don't envision myself ever sitting in an office having somebody feed
9 me reports that I'll go over to make sure everything's going okay. I
10 guess I'll produce these reports for the USDA inspector. I, myself,
11 will go out and inspect the plant myself and make sure that
12 everything's going okay. Thanks for your time.

13 MR. BILLY: Art?

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

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

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

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

1 MR. SMITH: Let me check.

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

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

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

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

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

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

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

1 importance but --

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

4 MR. SYRING: Correct.

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

8 MR. SYRING: They're not selected.

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

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

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

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

1 selectively treated with chlorine.

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

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

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

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

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

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

19 MR. CLOSE: Not in our plant.

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

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

26 MR. BILLY: I'm going to -- again, I appreciate this but in
27 fairness to everyone what I'd like to do is suggest that you folks get

1 together separately and share the data and the information and anyone
2 that's interested you're welcome to participate in that. There's one
3 more speaker. Bruce? Thanks for being patient.

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

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

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

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

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

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