MR. BILLY: I would like everyone to take their seats, please. Okay. Good morning, everyone. I'd like to get started, please. The -- the schedule for today calls for us to focus on two related issues. One is the issue of layering as it has been characterized. That is, the relationship of the proposed new requirements to the requirements, and also the idea of a shift to performance standards and away from the more traditional approach of command and control as the means of spelling out industry -- requirements on industry and holding industry accountable for meeting those command and control type requirements.

What I plan to do is to first have Mike Taylor set the stage in terms of the paper that was provided and try to characterize our approach, the current thinking of the agency in terms of the concerns, the issues that have been raised in this area.

We then plan to have Ralph Stafko talk about the regulatory reform package because it is the mechanism by which the agency plans to proceed to clean up the current regulations, convert those that need to be converted to a HACCP based or HACCP compatible type approach, eliminate others, and the other types of changes that were -- we're planning to make.

Pat Stolfa will then talk about performance standards. We got into it a little bit yesterday, but we would like to provide a much more in-depth view about performance standards, about what they mean, how specifically we would change existing regulations that hopefully all of you are familiar with to a

performance standard type approach.

In that regard, I think to the extent it's appropriate to then look backwards towards yesterday's discussion and talk about what inspection would do in terms of performance standards and what role inspectors would play with regard to a performance standard type of approach would be very germane, and so I would encourage us to do that. As we talk about some of this new approach, let's look backwards, and things that we talked about yesterday in the context of layering and performance standards are very germane in terms of the dialogue that we'd like to have today.

Again, I wanted to make a few announcements. We're not as crowded today, but for anyone that's interested, there is an overflow room where we are -- there's a TV where we're telecasting the session. You can watch and listen to it. That's room 4347. It's available to the public, to anyone, agency employees, or anyone that would like to use it.

If there are other people that you have that haven't come because of concern about space limitations, they're welcome to come, and this will be consistent throughout these sessions. So we'd like as many people as possible to observe what's going on and to if they choose to to participate.

In terms of the schedule for today, again, I'm going to run this first segment until about 9:30. I think several people have encouraged shorter breaks, and I'm going to do that. Maybe 15 to 20 minutes, and depending on the progress we make

through the morning, make a decision about the length of the lunch hour.

The important thing is to have all -- a full discussion on all of these very important issues.

MS. MACKLOW: Tom, can I raise a point of order?

MR. BILLY: Sure. Sure.

MS. MACKLOW: On September the 14th on the current scheduled, it talked about the regular -- the regular -- performance standards, quote, layering. Tomorrow, you really get into detail in terms of performance standards and microbial testing, and I think that there are some people that are planning to come tomorrow that are not here today to address that issue in some depth, and I think it would be very unfortunate if we got into the very in-depth performance standard discussion today that really is intended tomorrow.

I think your today's discussion on performance standards would be very summary and maybe a philosophical content, but it's not the day for getting to the down and dirty -- you know, the devil's details if you will.

MR. BILLY: I should make that very clear. We do not plan to have the discussion about micro -- performance standards and microbial testing that's scheduled for tomorrow today.

MS. MACKLOW: Yes.

MR. BILLY: Our focus today is more the philosophical underpinnings of performance standards and then examples that are associated with existing requirements and how -- how using

those examples, it will be an indication of how the program will shift, how some of the current inspection procedures are going to change. Current tasks that inspectors carry out will not be continued. Other tasks will take their place, and -- so that in that sense, in the context of layering or that notion, it will -- I think it will provide a better understanding of the kind of changes that are going to occur with regard to the current requirements, and that it's not just what's -- putting the new requirements in the form of performance standards. It's going back into the existing regulations and wherever possible converting existing command and control requirements to performance standards.

So it's that latter part that will be the focus of today.

MS. MACKLOW: It's just a concept discussion.

MR. BILLY: Yes.

MS. MACKLOW: I just wanted to clear that up. Thank you.

MR. BILLY: Are there other questions about that or the agenda?

MS. MACKLOW: I'm the only one talking this morning.

MR. BILLY: No, I don't think so. All right. Well, with that then, I'd like to ask Mike to set the stage with the agency's thinking with regard to layering and performance standards and reg reform.

MR. TAYLOR: Thank you, Tom. Let me just say first that the Secretary as well as the Deputy will be spending time with us today and will be over later. The Secretary's schedule was

disrupted yesterday by a cabinet meeting, and that is also requiring some follow up by him with the sub-cabinet within the department this morning, but he will be spending time with us.

I want to really make some very general comments about the subject for today's meeting because as Tom said, Ralph Stafko and Pat Stolfa will be talking about some of the substance, but I do want to really try to put this discussion in context, and it's really the context that I talked about a little bit yesterday regarding the fundamental shift in our whole regulatory strategy that is embodied in HACCP.

And I would say to Rose Mary, I mean it is the -- the whole issue of shifting from a command and control approach to a more performance standard based approach is a very broad shift in the program, and it goes way beyond the issue that we're going to talk about tomorrow of specifically how we move towards performance standards targeted at reducing harmful bacteria because we have a whole system of regulatory oversight that is currently based on a whole array of command and control prescriptive requirements that have the potential to be converted to performance standards in a way that we believe will dramatically improve the effectiveness of the system.

And this is a shift that in our mind is really compelled by the whole philosophy of HACCP which again is about more clearly delineating the industry's responsibility for building the safety controls into a process, to produce safe foods in accordance with some appropriate safety standard. HACCP is

based on the plants taking responsibility for designing controls that meet a performance standard if you will as opposed to the government prescribing in detail who a company is to go about producing a safe product.

And we will have a very concrete example of the nature of the shift that we've got to be considering when we talk about the proposal that we're developing to amend the current regulations concerning cooked meat and poultry products to incorporate as an alternative to the current command and control prescription of times and temperatures, an alternative performance standard articulated in, for example, degree of lethality required to be consistent with what's achieved by the current command and control elements of that regulation, but that would leave it to the company to design the specific control that in their process for their product would work the best, meet the various needs that a company might have for designing a process to produce a safe product, meeting an acceptable performance standard, and you know, Pat will talk about how we've approached that.

But if we're going to have a HACCP system in which plants are designing process control plans, developing HACCP plans and designing critical control points, we have to operate on the premise that wherever possible, we should not be prescribing the critical control points. We should be articulating the performance standard outcome that a HACCP needs to meet, and then holding the plant responsible for designing a system of

controls that meets that standards.

So again, performance standards as we see it, this shift goes way beyond tomorrow's topic. It is the whole really philosophical regulatory construct that we believe will work best to improve food safety, and the reason we're so focused on this is not only is it conceptually consistent with HACCP, but we really do think it has enormous power to improve food safety because rather than having the government be in the business based on whatever its current state of knowledge is about how food can be produced safely, the government being in the business of prescribing how you go about your business.

Instead, we can articulate really on behalf of the public what's an acceptable food safety outcome, and then harness the innovative capacity and the technological sophistication of the industry to design processes that will meet that standard, and we think that is all part of putting the plants in the position to do their job as well as they can -- that is, producing safe products in a manner that meets their various constraints and needs -- but also put us in a much better position on behalf of the public to know whether a product is meeting an appropriate standard of safety because we will have articulated that.

We will be able to focus more of our efforts on verifying that plants are producing products and observing the controls they believe are appropriate to meet an identified performance standard. We think this just has enormous power to improve food safety.

It also has power in our view to improve the way in which we use our resources because, again, rather than focusing as much attention as we do now on the -- some of the details of how companies go about their business, we'll be focusing more of our attention on whether companies are achieving the acceptable outcome which is really what consumers care about is the safety and quality of the food that's actually delivered to them.

And that's why our regulatory reform initiatives that we'll be talking about this morning a little bit include addressing some of the so-called prior approval systems that we operate whereby, currently, we require a plant to submit in advance for approval by FSIS blueprints, establishment specifications, so that before companies build new plants or modify existing ones, we have to approve the blueprints in advance. Equipment, similar sorts of approaches and partial quality control plans. We have prior approval systems for all of that.

When an environment in which we're seeking to more clearly have industry take responsibility for the means of meeting appropriate performance standards, we need to consider whether those prior approval systems are really consistent with that so that you know, rather than having the government take responsibility for whether a plant is set up in a manner that enables it to produce sanitary -- produce food under sanitary conditions, we should be simply holding the plant accountable for producing food under sanitary conditions.

So we're proposing to eliminate some of these prior approval

systems, and Ralph will be talking about that. This, again, will also in our view contribute to making better use of our resources, and I'm referring not only to the resources involved in actually implementing that prior approval system in terms of the reviewers here in Washington and the time spent by our staff in the field in managing the approval process, but also I think support the better use of our in-plant inspectional resources because again, by virtue of just using the blueprint example, by virtue of having a prior approval system for the blueprint, to too great an extent in some instances, the issue becomes the blueprint and whether the plant's -- the design is actually in conformance with the blueprint as opposed to whether the design of the plant is such that the plant is actually able to produce food under appropriate sanitary conditions.

And so again, it's all part of shifting our focus to holding the plants accountable for meeting their responsibilities with regard to sanitary conditions and product -- and end product as opposed to micromanaging if you will some of the details of how the companies go about doing that.

So it's that fundamental shift that we want to be talking about and that we'll be addressing in today's discussion. One of the commitments that we've made, and this is just essential to the success of our initiative, is that any of these changes that need to be made to be consistent with HACCP, to make HACCP work, obviously, have to be completed before plants are

expected to implement HACCP.

And this is the basis upon which I, you know, readily say and have said that we're as against layering in this sense of putting HACCP on top of an existing regulatory regime. We're as against layering as anybody because we can't operate and companies can't operate under two such conflicting regulatory paradines.

And so one of the things that you'll be hearing about is that we've gone through already our regulations page by page and have identified and will be publishing in the Register here shortly a list of our -- our list of rules that we've identified as needing to be revised, repealed, in some way changed to be consistent with HACCP, and we're going to invite comment on what other -- what people think. You know, have we got the right ones? And we're going to go through a process of addressing those regulations as part of the transition to HACCP.

Let me just close by saying one thing more about what our objective is for the meeting today. We ought to be talking a little bit obviously philosophically about this whole transition, and if -- and get out issues that are on people's minds about the desirability of the transition.

I would also though really invite and urge people to provide just as many specific suggestions as they can about aspects of our current system that either should or should not be changed in the course of such a transition. We really would like to be

sure as we're going through our work, day by day, that we're getting the benefit of the most specific suggestions possible about what should and should not change about the current system as we -- as we consider this transition to performance standards.

So Rose Mary, I'm hoping we'll get a little beneath the surface, and perhaps you might even have some examples yourself before the day is over. I'm counting on you.

MR. BILLY: Maybe at this point, it would be good to just stop and see if there are any general questions that people have about what Mike has said before we get into the specifics of the reg reform package.

Are there any questions? Yeah, Ron.

MR. PRUCHA: Mike, is the list that -- Ron Prucha -- is the list of regs to be deleted or modified that you are presently considering, is it more extensive than what was in that backgrounder that was passed out yesterday?

MR. TAYLOR: Absolutely.

MR. PRUCHA: I mean, I'm talking about the labels and the blueprints and the product standards, and --

MR. TAYLOR: Very, very much so. We go through provision by provision. We've done that, and we've pulled out -- you know, I don't know what the number is -- dozens of specific regulations that aren't mentioned in the background paper but will be published in the Federal Register.

MR. BILLY: Dave.

MR. CARNEY: I was here yesterday off and on and plan on being here all day today, but I've never heard anything mentioned about egg inspection. You routinely refer to the meat and poultry inspection regulations but nothing about eggs. What's your intent on dealing with that?

MR. TAYLOR: The proposals, of course, address meat and poultry inspection, and the issue of whether we would move towards HACCP formally to carry out our new responsibilities for egg products is one that we need to consider. We're not at the moment really focusing on that. They are very different issues really in terms of immediate food safety needs imposed by egg products as compared to the array of meat and poultry products we regulate including the fact that these -- to a large degree, these are processed products that have kill steps.

But conceptually, obviously, HACCP has potential application there, and I think we're going to in due course have to look at that. We're really in the midst still of managing the transition of management responsibility for that program from AMS to FSIS, and we will -- again, we'll have to consider that sort of question in due course.

MR. CARNEY: Are you telling us that we may be looking at another mega reg related to egg inspection?

MR. TAYLOR: I'm sure it will be an extremely elegant document that would be produced. Thank you for your helpful comment.

MR. BILLY: Dave reminded me. Again, I'd like to encourage you to waive your name tag so we can keep a process going. One other thing I was asked to say and forgot is that we're pressing the limitations of the amplifier system, so what the control person is doing is when I recognize something, he has got to crank it up, and so there's a little bit of a pause while he does that, and sometimes they're missing the names of people.

So if you -- before you speak or say your name which I again encourage you to do, say one, two, or something and then do it. That would help. Patrick.

MR. BOYLE: One, two. See, I am trainable. As long as we're talking generally about this shift and the philosophy behind what you envision, I wonder if you could talk a little bit about your prior experience at FDA which is in many instances a performance based driven food safety system with regulatory oversight of a fundamentally different nature that what we've experienced in the meat and poultry industry, and how would you compare and contrast the in HACCP system that you envision once you've eliminated all the layering with the FDA model? What would be the similarities and what would be some of the major differences if any?

MR. TAYLOR: That's a huge topic, and the problem is you can't -- it's very hard to make a general comparison because I think you have to look at the subsets of the industry, the very diverse array of industries that FDA regulates and what a HACCP

system might look like in the end, you know, for certain industries that FDA regulates. Baked goods, for example, would be radically different in certain -- in many important respects look very different that a system that we might implement.

And I -- maybe you ought to help me understand what you really -- what would be helpful to you in this discussion so that I just don't start talking on because I -- it's just such a broad question.

MR. BOYLE: Well, to make it more specific and perhaps more comparable to the meat and poultry and egg products within your jurisdiction, you were actively involved -- both you and Associate Administrator Billy in the development of the HACCP proposal for the seafood industry at FDA. How would you compare and contrast that proposal, assuming it's implemented the way you proposed it, with your vision of a HACCP based meat and poultry and egg products inspection system once the layering that you want to eliminate has been addressed and resolved?

MR. TAYLOR: Let me -- I'll say something general, and then Tom's the real expert on that, and maybe he would like to reflect for a moment on that.

Conceptually, in terms of the HACCP principles and the concepts of clearly delineated responsibility and so forth, I mean, there's full compatibility. And so I don't think you'd see -- I mean, there would be no sort of conceptual difference

there.

Obviously, and again Tom may -- can talk about this better than I, but there's a far -- far broader array of diversity of products, first of all, species that would be subject to the FDA seafood document and a far more diverse array of hazards that need to be dealt with, and so FDA is taking certain approaches to assisting the industry in identifying hazards that, you know, we -- that may end up being somewhat different.

But the basic -- same basic concepts of HACCP and -- you know, would I think -- I mean, it's very compatible. Tom?

MS. MACKLOW: I'm sorry. I didn't hear that. Are you -- with FDA with the seafood?

MR. TAYLOR: In terms of just the number of different species that are, you know, used for food and the -- consequently, the array of potential hazards is just far broader in the seafood arena than it is for meat and poultry.

MR. BILLY: Probably the best -- the best example of that is if you were to look at the hazards and controls guide that the Food and Drug Administration produced for assisting the industry in doing the -- both the hazard analysis and the development of their HACCP plans, the guide is dominated by the array of potential hazards associated with about 500 common commercial species, each of which bring a different set of hazards to the table in terms of consideration.

Fin fish, shellfish, warm water, cold water, and it's not just those that are off either fresh water, lakes and rivers,

or off our shores, but from throughout the world. The United States depends -- about 55 percent of the seafood consumed is imported from about 140 countries.

So it's not just the hazards that might be associated with the effluence coming out of the Mississippi River in terms of what's harvested in the Gulf of Mexico, but off the coast of India or Japan or Australia, whatever.

So it presents a -- because of the wide variety of species a whole different set of hazards -- potential hazards that must be considered.

When you shift from that area and dealing with that aspect in terms of what the processing plant must think about in terms of raw material coming in the door if you will, to the processing itself, then you all of a sudden see a great deal of similarity in terms of the potential hazards associated with thermal processing, just if you will a slaughter type operation, cutting pillets, or other types of common processing procedures used for seafood products.

And in that sense, there's a great deal of similarity, the similar kinds of hazards, similar kinds of cross contamination problems, and so forth. Once you leave the processing plant then, there's -- there's a great deal of similarity in terms of transportation, what happens at the retail level, and so forth.

So it parallels pretty well beyond that, and I think that what you're going to see in terms of a final rule for seafood will be very similar to what was proposed for meat and poultry

in terms of following the seven principles, the actual mechanics of HACCP, and that kind of thing.

FDA also in its hazards and controls guide identified all of the existing regulatory requirements in terms of pesticide residues, microbial standards that are in place for, like, the zero tolerance for salmonella in seafood, and other similar kinds of existing regulatory limits or requirements that are in place, and the intent there is that those requirements are the performance standards if you will that the agency would intend to hold the industry accountable for in terms of their HACCP programs.

So control measures designed to accomplish meeting those regulatory requirements or standards are part and parcel of that regulatory scheme that has been proposed and is in the process of being finalized for seafood products.

So in that sense, there is a very close parallel to shifting what we'll be talking about today -- shifting a lot of the existing regulations here for meat and poultry to the performance standard type approach, and one of the benefits of that being then the flexibility of the industry to decide how they're going to accomplish that with a HACCP type strategy.

MR. TAYLOR: Patrick, let me just add one observation to relate this topic to today's discussion in terms of -- in the comparison between what we're doing and FDA is doing in the transition to HACCP. FDA has never exerted the kind of command and control regulatory oversight of food plants that this --

the Food Safety and Inspection Service has exerted over meat and poultry plants, and that reflects the very different histories and very different statutory regimes out of which these two programs have evolved over the years.

So FDA has less to do in terms of getting rid of command and control regulations because they have less to deal with, and they already have in place, as Tom mentioned, performance standards that HACCP can be the process control basis for achieving.

So that aspect of the transition is somewhat simpler at FDA than it is here.

MR. BOYLE: One final comment. It'll go directly to the comment you just made, Michael. At the end of the process, years from now I suspect, setting aside the statutory differences, is your vision of how this industry should be regulated at through FSIS similar to how you envision the HACCP proposal being implemented for the seafood industry at FDA?

I mean, what would the role of the inspector be under your vision of HACCP once we've gone through this transition here, and is it comparable to what you envision at FDA and the seafood industry?

MR. TAYLOR: I think it's -- that's a fairly complicated question. Let me deal with two different aspects of it. In terms of oversight of HACCP, specifically, and looking at the question of the role of inspection conceptually, I mean, they -- you'd envision similar constructs.

I mean, let's be -- let's be real clear. FDA is operating under severe resource constraints with regard to the -- its inspectional work force, and that is -- and that is a real issue for the future with respect to the seafood program.

So -- so that's why I say looking conceptually at what the role of inspection ought to be in terms of the roles we talked about yesterday, validation, verification, enforcement, and looking at the oversight of HACCP specifically, and conceptually, you think in general -- you know, they'd be conceptually the same.

But again, you have to recognize seafood and the safety issues posed for particular species differ from the issues posed for the particular species we regulate, and so it's not as though you can -- it's a lock step sort of everything is the same, but conceptually, HACCP and HACCP oversight ought to have some commonality.

We have a statutory mandate to carry out carcass by carcass inspection, bird by bird inspection. That really is addressing an array of values that include but go beyond product safety, and so that's why -- I mean, that's part of what makes it a complicated question, and there are a lot of good reasons, you know, why that examination of carcasses in meat and poultry plants -- some approach to ensuring that carcasses meet wholesomeness standards as well as standards has historically been an important part of our program, and my -- I mean, my expectation is subject to, you know, anything Congress might

choose to do, is that that concern or the set of values there will remain part of the program and subject to some kind of inspectional oversight.

I don't know if that's helpful, Patrick, but --

MR. BILLY: I'd like to add something. I think in the context of a regulatory strategy for seafood -- again, as the example we're talking about that reflects a farm or water to table approach. FDA is the head of our agency. There are several examples. One example being with shellfish where because of the nature of shellfish, there's actually a need for control measures to decide whether shellfish can be harvested, that are very unique to shellfish. FDA in cooperation with the states have a regulatory regime that's long-standing to address that.

FDA also deals with inspection of vessels where there's particular hazards that are -- where it's necessary to do that unique to certain species again where those hazards exist, and there are certain species as an example where just harvesting them and leaving them in the net too long will result in a production of a toxin, and so it's important what the practices are on the vessel.

And then on the other side of processing where in fact part of our strategy with regard to transportation and retail is to take advantage of the years of effort FDA has put into working the states to bring better regulatory controls and inspectional activities to the retail level, and so it's -- you know, it's

not all one or the other. I think in that instance, part of our thinking was influenced by that kind of strategy that is actually a long-standing one in the Food and Drug Administration.

Yes. Katie.

MS. HANIGAN: Katie Hanigan with Farmland Foods. Question for Mr. Taylor this morning. Good morning. Once we're through with revising and deleting regulations, making them more compatible to HACCP, will this eliminate regional notices to our plants?

MR. TAYLOR: Bill Smith can deal with that --

MR. SMITH: What we want to use or are moving to with our notices now, especially in HACCP, is instructions to our employees, and what we want to do is have a shift there also of not -- we want the requirements, the regulatory requirements and the standards to be in the regulation, and notices to serve only as the function as instructions to employees on how to carry out those responsibilities and not interpret or add additional requirements that are not in regulations.

I think sometimes we -- or pass directives and notices may have put in that arena. We are moving specially now that these would be instructions to employees on how to carry out their responsibility.

MS. HANIGAN: Thank you.

MR. HENDRICKS: Good morning. Two, three.

MR. BILLY: Four, five.

MR. HENDRICKS: Is it on now?

MR. BILLY: Yes.

you pick me up? Okay. My name is Lamar Hendricks. I'm with Hillshire Farm and Conn and I'm the director of regulatory compliance for that company. We produce a large -- a large amount of cooked sausage products.

With Hillshire Farm and Conn, being the director of regulatory compliance, it's part of my responsibility to go out and interpret all of the policies and memos and regulations for our plants and to help them implement these things into the plants.

It's a job. When we look at inspection tasks, I think that inspection oversight should continue under HACCP. I'm not -- I'm not for doing away with the inspection, inspectors, and some of the things they do today, but I do believe that the frequency of verification can be modified depending upon the complexity. I think it has to do more with public health risk and very importantly the history of compliance for that facility.

I think if we do a good job, I don't believe that we need an inspector in there all the time. We don't, but I want those inspectors to audit our programs, audit our food safety systems, and help assure us that we're following those HACCP programs.

Just as I'm going to go out and audit our facilities, I want those people to be there to do that as well. I think the role

of the inspector would shift to verification of food safety systems, and it should be towards critical control points within the HACCP program.

When we talk about a regulatory shift, we've got to do something to take it out of the current manner in which we do business. We can't layer these things on top of what we're currently doing now, and I'm not talking so much specifically about doing away with labeling or some of these other systems that we have today although I think we could cut down tremendously on those things, and there's some good things about those.

I like the idea that we can go in and talk to -- well, I guess Roy Oyster or some of these people who've retired now, that we can utilize some of their expertise in our systems. I worked with Mike Donovan and these people. I need to be able to talk to those folks, but I don't necessarily need them to approve every single label that goes through our system.

When we talk about packaged product compliance, I think the department really did a good job when they went and asked their top to bottom review people to go through and look at all these things. These are the people who know what's going on. Not -- well, I don't know about the top so much, but I deal a lot with the other folks in this administration.

But they have recommended, and I have not read the 600 pages of material, but I have read some of the short summaries, and last night, I listened and I went back and thought about this,

and it seems like this task force has suggested a separation of economic and safety issues, and I made a few notes about it.

Current inspection tasks such as checking net weight, declared count, nutrition labeling verification, compliance with product standards, PQC programs can be I think accomplished much more efficiently than the current system. Maybe through the use of statistical sampling programs, charting, and other QC tools.

I think many products from different plants could be monitored either at distribution centers around the country or retail outlets, and I think some of those functions that we've done in the facilities could be done much more efficiently -- and I'm talking about -- I could check if I was on this team of inspection personnel, I could check just about everybody in this room within a week as far as nutrition labeling. Verification, protein, fat-free control programs, fat in the added water. If they wanted to do microsampling, they could do that.

You can do so much more so much easier than the way that we're doing it now. And I think -- I mentioned some of the approval systems that we have. I get a lot of -- out of food labeling divisions, I get some good help from those people, but like I said once before, we don't need them to stamp everything that we go through. We don't need to argue with them on whether this product is in compliance.

That's where you go back to the history of compliance. If

the plant is doing what they're saying they're doing, and they're performing in accordance with the law, then that should be enough.

When you talk about patrol assignments -- I heard some of the inspectors talk about patrol assignments -- and I've been in the industry thirty-some years -- a lot of those guys are on patrol assignments right now. They're not in that facility every day. If they need to be, they need to be there. If they don't, they don't, but let the history of compliance for that facility, the auditing systems that we have or that we plan to have utilize those people properly.

MR. BILLY: Alan -- this is setting the stage for the more detailed discussions, so a couple more and then anyone else, we can get back to it. So Alan?

MR. OSER: Is this thing on? Okay. Alan Oser from Hatfield Quality Meats. I applaud what you're doing in Washington here with the regulatory review. This is all stuff that has to get done, but I would caution you that defeating or meeting this layering challenge here is not equal to decentralization of authority.

If we simply eliminate blueprint approval and equipment approval at the Washington level but throw it back into the hands of your in-plant inspectors, you haven't really changed anything there. All you've done is decentralized. And when you decentralize, the ability to keep things on a fair and even plane, the ability to control these kind of things from a

management standpoint become less and less.

So I would hope as we're fooling around with some of these things, whether it's label approval or these other items here, that we're really accomplishing this process of removing layering, and we're not just decentralizing. Because I think if we decentralize, and you lose control at this level, it's just going to make things much, much worse.

The trick here is really focus. The industry is concerned about the elimination of regulations but less so than what's going to happen when the rubber meets the road which is in the plant. It's absolutely essential that the inspection effort be walking in lock step with this HACCP effort in the plants. This has got to be a partnership, not a competition.

We can't go into this with the mind set that, well, we don't know if this thing's going to work or not. We're kind of going to have this HACCP plan running, and we'll do our thing, and the company will do their thing, and if don't like what we see -- you know. It's not going to work. You might as well not even do it. We're either kind of in this together or we're not, and I would caution that as we are decentralizing here, we're decentralizing for the right reason.

When you go to -- being a veterinarian does not make you an expert at reading blueprints. I would suggest that our veterinarian and myself, neither one of us can probably read a blueprint, and the company is about to spend $2 million, $3 million, $5 million, $8 million on a facility. They need

somebody to sign off on this thing that when it's -- when the concrete's poured, they're not going to have to come back with a bunch of jack hammers and rip everything up.

So these are some of the hard issues that you're going to have to deal with on these subjects.

MR. TAYLOR: Alan, let me just reiterate the concepts here, and I will use blueprint approval to illustrate the concept underlying our proposal.

The concept is not decentralizing of the blueprint approval process. It is getting the agency out of blueprint approval as a mechanism for carrying out our food safety oversight responsibility, our sanitation oversight responsibility, and the important underlying principle is that the plant ought to be responsible using whatever resources and expertise are available at the plant design stage for designing a plant in which they can produce products meeting the sanitation responsibilities that exist under the law.

I mean, one of the issues that we ought to be talking about in the course of the day's discussion is if the principle is get FSIS out of the blueprint approval process and shift our focus including the focus of our inspectors, not from whether, you know, some feature of the building is consistent with the blueprint, but rather whether the plant is operating under sanitary conditions, what role should we have in providing guidance or, you know, assistance answering questions?

I mean, that's another issue, but let's be very clear. The

proposal to get us to eliminate the prior approval system for blueprints is not to decentralize the prior approval system but to eliminate it. We will be out of the business of approving blueprints as a regulatory matter.

MR. BILLY: Dave.

MR. CARNEY: Is it on? Dave Carney with the National Joint Council. I'd like to address the concern that Katie had about regional notices. If top to bottom is taken seriously, there should be no regions in the future to issue notices.

Speaking of top to bottom, there were ten teams on that, and I received some summaries of those teams, and there was a deadline for those summaries to be presented. I see nothing to deal with day one, and day one is a very serious issue on how inspection will be conducted once HACCP becomes a reality.

So I want to know what the status of day one is. It appears day one has now turned into the longest day.

MR. SMITH: Well, we spent a lot of time yesterday talking about day one. Day -- day one -- we have published a proposal identifying certain dates to -- that are going to be met, implementation dates, for both the near term and for bringing particular processes under the HACCP proposal.

So day one essentially talks about implementing that proposed rule under the existing structure given that we -- given the time frames that we have so that you would have recognized that we have regions, we have areas, and we have circuits because that's what exists now. That is what we'd have to implement

under that structure, and so that is why day one has been separated from top to bottom because that has been built around implementing under the existing structure and letting the top to bottom piece work so that if there's change, that it would come through that mechanism.

I mean, in what the inspector role, the tools -- we're planning to use the inspection support system in PBIS. It would be used at least on a day one activity. So it's using a lot of what exists today, not in a layering mode, but taking what we can use, the assignment of inspection tasks, and recording of inspection results, and classification of deficiencies using existing systems at this point to carry out the very early implementation, and that's different than top to bottom which -- which looks at different ways of being able to carry out things but may be on a longer time frame.

So that's why day one has been separate from the top to bottom issue.

MR. BILLY: A way to think about characterizing the day one is that it's a planning exercise to figure out, and recognizing it's contingent on what final decisions are made about what the actual requirements are in the final rule and what the actual time frames will be, and there's an awful lot of comment and discussion in these meetings that will impact that.

So -- but regardless, in terms of the kind of changes that are constituted in the proposal, it's necessary for us to lay at least some planning around how we would get all the training

that needed done, how we would change the existing directives and inspector instructions, and so forth to make this kind of different approach work.

So the day one exercises are really built around doing some of that preliminary planning so we're prepared to meet whatever is necessary and actually moving forward to implement this.

Katie?

MS. HANIGAN: Kim has got a question.

MR. BILLY: Okay.

MS. RICE: I've got a question for Bill. Could you explain to me how what you just described for day one is not layering if you're going to use your existing systems and --

MR. SMITH: Using the existing support systems. As an example, I can give the process O-1 -- I believe that's the first process that is implemented 12 months after the final rule as proposed now -- talks about raw ground product, and currently, in our present inspection system guide, we have at least seven critical control points under process six if you're familiar with those.

So we address raw product under the sausage part. We address it under the ground beef part. We address it under the miscellaneous which includes the poultry and several others, and we also address it at that point in our inspection system guide, receiving, and then on the other end, storage and shipping.

If those are all critical control points, then we get into

the process of verifying, as I said yesterday, the complete system, and so now your inspection task would focus on the verification of the records of the CCP monitoring records or the CCP -- some on-site monitoring of the CCPs. Again, then record process review of the plant verification activity and also on-site of the plant verification activity, hands on.

What that means is then if you're in that mode, and that's covered under the HACCP plan, you would shut off or delete those tasks then that are presently exist. The time probably won't change a whole lot because the inspection tasks now would go -- we would picture could take -- or five and ten minute tasks -- looks something specific now, looking at this process overview concept and make an analysis.

We could have, you know, tasks could take an hour or so, but it's looking at the whole at one time and not repeating the duplication. If -- if you have cooked sausage and cooked hams and roast beef, and they're all under the process category of cooked -- fully cooked, not shelf stable, then there's no need to look at the cooking of each one of those products. You need to look at the process complete, and then -- and make a determination whether all those products are in control or not in control.

Whether cooking is in control for all the products that are in that process instead of looking at each product individually and making that determination. So that's how we would shift in that mode.

MS. RICE: It sounds to me -- you use the term CCPs when you're talking about fresh ground product for shipping and storage, and it -- does that mean that you've already determined what our CCPs should be?

MR. SMITH: No, no, no. What that means is you're going to identify the number of CCPs, but in our current configuration in the ISG, we have categorized certain, and so wherever the plan, HACCP plan comes up with it, CCPs -- wherever they're duplicated in the current system, then we cover those under the valid -- the verification activities, and once we have done that, then there's no need to duplicate those under the existing monitoring plans, so those tasks specific to that would be turned off.

MS. RICE: How will you handle where you have something and we don't? If you've determined if the CCP in our model shows it's not because you've previously determined it is, does that mean it is?

MR. SMITH: No. If you have in your plan that you're going to have a process for raw ground or for -- or cooked sausage, that is defined under the processes of what products going under that in the regulations, and therefore, then we've said that we are going to verify your process to control that.

That means any association we have right now currently in the ISG for that process would be turned off as that comes on line. So we're not going to dictate what those particular -- we're going to verify what you have, and that's what we tried to say

yesterday.

We're going to be verifying the CCPs that the plant puts in place because we already have validation. If the plan is validated and it proceeds past the, you know, the validation step, then we know we have a process in place to produce a safe product.

Then we're going to verify that that's being followed, and so we don't need to schedule a ham temperature check because somewhere the kill step that's associated with that process will be monitored in the -- in your HACCP plan, and that's where we would pick up that monitoring responsibility.

So there's no need to verify it and then go back and do a product specific task. That would be duplicative. So that's why -- that's what would be shut off.

MS. HANIGAN: Okay. I've got another very basic question. Yesterday, we went back and forth on the inspectors' role, verification, validation, and I think we need to clarify it this morning.

When the inspector is validating our HACCP program, is that or is that not approval in your eyes? I want to know are you telling the inspector they are approving the HACCP program or they are validating it because I think there's a lot of views here on the table.

MR. SMITH: The inspector will be validating the HACCP plan, and that means that he -- he or she will be looking to see that the seven principles that are proposed in the regulation have

been addressed in that plan.

MS. HANIGAN: It is not approval then.

MR. SMITH: No.

MS. HANIGAN: Thank you.

UNIDENTIFIED PERSON: How do you -- this is Jim --

MR. TAYLOR: If I -- Jim, let me just -- let's -- in the effort to be clear, let's talk about this just a little bit more because -- I mean, I know that there's some who view our inspectional oversight in a validation mode with respect to a HACCP plan to be the functional equivalent of our approving plans, and let's just talk about that a minute.

One thing we said that we don't intend to do as the -- as we transition to HACCP is set up a process whereby in advance of operating under HACCP, plants submit plans to us which we then approve in advance of those plans being put in place and operating, and so in that sense, we are not engaged in prior approval. We won't have an approval system for plans.

On the other hand, we will be in the mode of providing inspectional oversight in the three modes -- again, as our current thinking that we described yesterday -- of validating that plans are appropriate, adequate validated HACCP plans, then verifying their operation and take enforcement actions appropriate.

If in the validation mode, carrying out our inspectional oversight role, we find that a plan has not been properly validated or does not meet the HACCP principles, we will take

appropriate action under the regulation to see to it that that happens.

So I don't want us to get sort of into a semantical confusion here by trying to reduce our role to the sort of simplistic, are we going to approve or not approve, because if in a validation mode, providing that oversight, we judge that the plan doesn't meet the requirements of the regulation, then we will take action to see that it does.

Now, that's what we have in mind, and that's what we ought to be talking about, not simply are you approving or not approving. That's the functional sort of concept that we have in mind for our oversight at the validation stage.

MR. BILLY: Okay --

MR. TAYLOR: Let me just say, we'd welcome some comments. If there's thoughts about is that what we ought to be doing, is that what we shouldn't be doing? I mean, let's have that conversation.

MR. BILLY: Waive your flag and you'll be --

MR. BERNARD: Thank you. Are we powered up down here? Thank you. Dan Bernard, National Food Processors Association.

Let me start because I wanted to talk about layering, and I've had some comments about that because it's where we started, but this last discussion on verification and validation -- I mentioned some of these things yesterday, and Katie has brought it up again -- and it's obvious that we're not in absolute agreement on what is here.

The agency has developed what might be called generic HACCP plans for certain commodities. It doesn't -- you have to do that. We recognize that you have to have some idea of what is acceptable before you go to the field with a plan. You don't have to look at this and say, well, we're just going to take anything industry puts on the table as okay.

That's not going to happen. That's not real world. We recognize that the agency is going to have to have some idea of what to expect when it goes to the field.

Now, if a firm that you happen to review has a different plan than what's your expectation is, that's where in my opinion the validation process kicks in. Why is this plan different? Let me back up a stage, and I think that before the agency goes to the field with what you thing ought to be there, those ought to be consensus plans. They should be reviewed so that we have some idea of the science behind those plans rather than just have the agency put together what they think is right.

Once we get to that point, there has got to be some discussion, and this is why in our comments we said there has to be some dispute resolution mechanism in place because you're going to go out there, and you're going to find a lot of differences in HACCP plans because they are individually developed. Some are going to be good. Some are going to be not so good, and you're going to have to work through that in the validation process until you come to say, well, this plan is okay. We think this is -- will meet whatever performance

criteria are your expectation.

Once that is done, then the inspectors in the field are fully capable and should be authorized to verify, conduct, whatever activities need to be done to verify that that plan is being followed day in and day out.

That is the way I see those terms, and that's what I understood when I read the documents that were presented and that came out of the day one group and have been incorporated into the top to bottom review. That's the way I understood that. Now, if that's not correct, then I think we ought to go back and revisit that.

MR. BILLY: That's correct.

MR. BERNARD: Okay. Can I go on to layering then? Excuse me. Both Lamar and Alan Oser have hit at what I think the target of this exercise in determining what it is we're going to change should be, and it gets down to what is going to happen in the plants. We can talk about blueprint approval. We can talk about all kinds of things, but I take you back to my comments yesterday.

I'm going to preface this remark by reminding you that this is not about inspector jobs. This is about what inspectors do once we have put in place a different system, and everything that we do should support that system which means that the people on the front lines have got to understand the system and have got to conduct their day to day activities such that the system itself is supported.

In far too many plants, the operation has been reduced to a single critical control point, and that is whatever the inspectors happen to be emphasizing in that region on that particular day. The system has got to be changed such that plants are encouraged and allowed to assume the responsibility for the safety of the products that they produce.

In our opinion, the system has taken that responsibility and placed it squarely in the hands of the inspectors, and that's not an entirely bad scenario. I mean, we've all agreed that we need inspection and that there is a need for oversight.

But until that responsibility is fully placed back on both shoulders, the inspectional force and the agency as well as the industry, HACCP is not going to be a productive vehicle. The changes and the layering that need to be considered should be targeted toward that.

Plants should be fully empowered to make the decisions on the safety of the products and to react to those rather than the current system which has, for some reason, placed the entire burden of the safety of that product on the inspectors. We leave it to the inspectors to find things that are wrong because that's what the system encourages, and that should be the target of changes that we need to make.

Thank you.

MR. SMITH: I just want to reiterate a couple of things you said. The validation that we'll be training our inspectors to do -- again, goes back -- we're not -- we don't have any set

plans at this point. Generic plans will be made, but they are -- and they are going to be offered to the industry, certain segments of the industry to help them do their program.

What we're going to be doing with inspectors is asking them to on validation to see that a hazard analysis has been conducted. The critical control points -- and after those hazards have been identified, the critical control points have been established to control those hazards, the critical limits are set. Then there's going to be monitoring activity however the plant decides that monitoring activity is going to take place, that there's going to be records kept, and that there's going to be corrective and preventive action identified for when the critical control point failed, and then what is the plant's -- overall verification activity.

So once we see that those seven points are in a program, and the critical limit we'll be looking for on things -- if a kill step that -- we want to see some kind of evidence that supports why that critical limit controls those hazards. Given that we have all that in place, then if something goes wrong, we will be training our inspectors, but the plant needs to take responsibility, and if a critical limit is not met and the plant tags that up and then reworks that product or redoes -- does something with the chill step to make sure that the product is safe, and they make the decision to ship that product, the only role we would have in that would be verification that that occurred, not that we -- that FSIS has

to approve the shipment of the product before it goes out.

That's a fundamental shift and change, so that gets us out of what we're doing currently with the roast beef which says if I have a cooking deviation, I call the regional director. If I have a cooling deviation, I call the regional director. That is not what -- the mode we will be in. The mode we would be in would be that if the plant -- if there's a cooking deviation, process in authority says either that's adequate or has to be recooked to a certain temperature -- and time/temperature. That takes place. That's documented that that's done. The -- first, the documentation would have to be in place to support why this is a safe process, and then that it met that process, and then that product moves.

The only thing we're asking under the HACCP system and verification is that there's record of that that we can -- either on site we will verify that or there's records that we can verify that that took place, and that's the mode we intend to be in.

MS. HANIGAN: Bill, I have a follow up to that. Okay? Training here is going to be critical then. For the inspector, obviously, training is going to be very critical, and I don't want to get way off base here, but 18 months ago, when red meat, pre-op slaughter program came on -- well, we -- it seemed like it should be pretty straight forward day one of that program, too.

And I guess we did have industry and agency training at

various locations throughout the country. I thought that worked pretty well. One of my concerns here, we're talking about the inspector's role, I read through your brief papers back to us, and understand that because of time and resources, industry will not be permitted to attend the training sessions that the inspectors are going to go to, and we're going to try to do this again in field sessions, et cetera.

Correct me if I'm wrong, but I think it's essential that when we get into the inspector's role that we need to have industry members there so that we all fully understand what everyone's role is because this brief six days that we're together is not going to cut it.

We're still going to have massive confusion as to what industry thinks and what the inspector thinks, and I don't think it's fair to either party, and I think you need to relook at the training, and when we're looking into a program of this magnitude, how much -- I know resources are tight, but how essential is it that we train correctly from the first step and not try to go back and retrain us or the inspector?

MR. SMITH: I agree, and that -- we're taking that into very serious consideration with the -- with the training development and understand that that -- that's an absolute necessity in order to have a successful program. So we understand that interaction has to take place.

MR. LOCHNER: Most of your examples you've been using deal with a critical control point that has an elimination step or a

kill step which I think are fairly straight forward examples. The real complexity in my mind is HACCP in fresh meat and poultry.

Technically speaking, if we just know where the hazards are introduced but do not have the technology to change them, then all's we're doing is writing a standard operating procedure and perpetuating the same hazards being introduced, and we're not going to see a dramatic change -- excuse me -- in product end point.

Is the agency considering getting involved in dictating process change where technology is available to force an improvement in the overall microbial quality, i.e., the frequency of pathogens on meat and poultry products?

I think we're kidding ourselves on fresh meat unless we analyze every step of the current process, where the technology -- ask the question, is the technology available to make an improvement? If so, let's make an improvement. Otherwise, we're not going to see an improvement in fresh meat.

MR. TAYLOR: Jim, let me offer sort of the philosophical answer to your question just given our current thinking about how to achieve progress. I think you make a very important point, and I believe that the industry has a responsibility independent -- and I think I hear you saying the same thing -- has a responsibly independent of anything we do as a regulatory matter to be working continuously to improve through technological innovation and every other means the safety of

products.

We're -- our approach is to say that the role that regulatory oversight can best play to foster that sort of progress is not by mandating, dictating in your terms the specific technology but rather by establishing performance standards with respect to the significant hazards associated with those products.

And what we need to take into account over the long term -- and we're -- you know, we specifically characterize our targets for pathogen reduction as interim targets for pathogen reduction because we're at the beginning of a process of putting in place performance standards for harmful bacteria on raw product, and in doing so, our contribution can be to take a count of where things are technologically.

We also need to look -- as we signaled in the proposal, the issue of what's the appropriate -- are we able to determine from a strictly public health standpoint what's the appropriate performance standard.

Our role primarily over the long term should be in articulating performance standards that provide incentive for the kind of technological innovation that you're talking about as opposed to necessarily dictating technologies. We -- you know, we know short term. We've put on the table the issue of anti-microbial treatments as an element of a system as we transition to the future, but as a broad philosophical matter, we should be about performance standards as opposed to dictating the means of achieving them.

MR. LOCHNER: Well, then I think when we discuss fresh meat, we might as well get on with it and tell us what the performance standards are going to be because I think a lot of debate -- and could be -- could be sacrificed and we could get to it if we were talking about the performance standards.

Just for an example, I think on layering -- and I was going to do this yesterday -- there's a tremendous amount of standards, particularly dealing with sanitation, that really do not contribute to product safety. If everybody wants to look up to this skylight in the center, you're going to see rust, and you're going to see peeling paint. Technically speaking, this room does not qualify to be an operational room, and we should cover every pitcher of water in here because we have a hazard.

The hazard that we have from that is no different in a meat plant than where we're sitting today, but if we stop -- and it should be corrected, long term, but short term, should we sacrifice two hours of production to correct that situation when I know very well that it's not going to increase the hazard microbiologically or physically to the product?

That's the type of issue we're going to be debating. If I polled everybody, and we looked up here, and I said it's unacceptable, normally I'd be arguing that it is acceptable, but I'm going to take the position that it is unacceptable, reverse my role. Half the people, seriously, would argue it's acceptable and unacceptable, but the reality is it made no

difference to the microbiological hazard of the product on that day, but that's the type of issue we got to get around.

So we focus on the things -- on the detail that does not make a difference, and we should be focusing on process and root cause that makes a difference. That's the transition we got to make. That's the transition the inspector has to make. That's the transition all in industry. It goes back to root cause. Where is the hazard?

If we know a process step contributes to cross contamination, we better correct it, and how aggressive you are in the performance standards and how equal you are will dictate how fast we get there. So I'm going to have a huge problem if we have gross differences in performance standards on fresh meat and poultry products.

MR. TAYLOR: Jim, let me just say again in terms of where our current thinking is on the specific sort of issue you raise here, and we got into a little bit of this yesterday in talking about the sanitation SOPs, and I think again, we've got to -- we've got a -- I mean, it's on the agenda for the 27th to talk about this in detail.

But the concept underlying the sanitation SOP proposal is to focus the SOPs on those conditions that pre-op or during operations relate directly to the possibility of product contamination, recognizing that there are other sanitary conditions that over the long term ought to be addressed, but we want to focus our efforts, our inspectional effort and focus

the daily attention of the plant on those critical sanitation issues that relate directly to the possibility of production contamination and increase the effectiveness of the system for holding plants accountable for meeting that -- those sanitation responsibilities very rigorously on a daily basis.

So we're -- that's the whole purpose of the sanitation SOP issue. You also put your finger on a real -- you know, something we need to work on, and that is -- and let's spend time on the 27th doing this -- what are those critical sanitation elements that ought to be the focus of a sanitation SOP that we would then use to rigorously hold plants accountable on a daily basis for meeting their sanitation responsibility.

And let's discuss that, but that's the whole shift that's embodied in sanitation SOPs. It's focusing our resources and yours and doing a better job of meeting those core responsibilities.

MR. BILLY: Yeah, I thought that David, Stanley, Angie, Mike Donovan, Nancy, Steve, Joe, Irwin, and Dane -- what I -- okay, okay. And Caroline and Alan again. All right. I got Jim. It's all right. I've got you, Jim. You're on there. And who else. Alan again.

Maybe now would be a time, Mr. Secretary, where you'd like to say a little bit in terms of --

SECRETARY GLICKMAN: Well, just -- I voluntarily sat next to this drip here. I want you to know that.

MR. BILLY: I don't think Jim has seen this but --

SECRETARY GLICKMAN: There is actually dripping --

MR. BILLY: -- there is condensation coming down that's dripping here in this container.

SECRETARY GLICKMAN: We did this to show you our serious budget problems here. Well, let me -- a couple things. One is that -- I regret that I haven't been here more. Unfortunately, when Senator Lugar calls or Congressman Roberts calls, I have to get over to the -- to the Congress because we've been negotiations on farm bill stuff, but either I or the deputy were going to make a conscious effort to be here most of the time, and of course, others are here from my office including Kim Schnoor who are taking copious notes.

Just hearing this last discussion, however, is a good example to me of the complexity of what we're talking about and the need for some precision in what the rules are like because otherwise, you know, it's kind of like quicksand. It's never ending, and one never knows what your responsibilities are, and yet, you know, in the normal regulatory climate, there's got to be some flexibility as well, but I recognize that we've got to send out signals where people have a reasonable certainty of what's expected out of them, and --

So in any event, I just wanted to say that we would be here and be assured that your comments are being analyzed and reported to me every morning. So I just thought I'd mention that.

MR. BILLY: David. Stanley.

MR. EMERLING: My name is Stanley Emerling. I guess I should validate myself. This is the first time I've spoken. I am a consultant. I had a meat business in northern Ohio which sold to food service, meat and poultry processing for 30 years. I came down to Washington 13 years ago, and ten of those years I have spent at the National Association of Meat Purveyors as its head.

Now, I'm a consultant, and Devin Scott who is sitting on my right who succeeded me in that position has asked me to make some comments based on the things we've heard referencing the experience that I've had.

And basically, I would like to go back into some of these inspection small business issues that have come up, and there have been things today that are germane to the comments I'd want to make. The drop of water brought up the condensation problem which is a very judgmental thing in many plants as to whether it, you know, the need to control that or not, and we're entering somewhat a no man's land from what FSI4 S calls a command and control and moving into an area of personal judgments, not necessarily knowing whether those who will make those judgments are as well trained, and that issue has been discussed, and then what you do when there's a conflict.

I have yet to hear yet today anything about an appeal process. How that will work, whether a plant will be closed down almost instantaneously, and a quick response time -- just

a date is a thing many of you will recognize the case sometimes is that it takes more than a day to get a response back in some cases. People are away from their phones, et cetera, and we need to have some kind of assurance that that won't happen.

You got into the questions, you know, of validating the plans, not approving them, and we need to know I believe whether there is also a question there what that appeal process will be and how quickly it will be resolved.

In small plants and many of our members are -- $25 million in business, and our industry is a very small business. Even getting up to 50 million can be considered small when you look at the scope of that, but they do make up a great preponderance of the plants that are under FSIS inspection.

The thrust of these meetings was really to address some of those small business issues, and a lot of the things that have been said here are certainly also germane to that, but I think you need to focus on how they impact. For instance, you know, we have food safety people. We have quality assurance people that are speaking here and very succinctly and correctly about a lot of the issues.

In a small plant, the fellow that runs it usually is buying, selling. He's going back to manage that the trucks got out on time. He's making sure that the product lines are correct. He's supervising almost everything. He has limited resources and few employees, maybe in our case, members of the National Association of Meat Purveyors, the average number of employees

is around 40. You have supervisors, but you don't have extra people. In many cases, can't afford it.

Now, I don't mean by using that word to mean that we want any kind of exemptions because we are just as dedicated to food safety and doing it right, and we want the people who don't do it right out of business. Now, that isn't even a very successful trend as we've seen it because they keep popping up under new names or something else or with different management, and that's -- that's an issue that needs to be addressed.

But we want due process, and sometimes you don't see that. You don't see that happen, and it needs to be incorporated into it, and regardless of what we do, if you don't really go from farm to table -- and as pointed out, you need the technological expertise and the way to do it and the testing, the quick tests, or whatever it is to do these things, but you got to make a dedicated effort because if -- if in our industry, we get rid of 100 percent of the problems you're worrying about, there may still be some problems out there. They've been documented -- people still get sick.

So though we have to do everything possible and maybe even beyond, you still need to watch that whole spectrum and put resources. We're concerned that the people you're going to have evaluating us, verifying us, need to have the same kind of expertise that is commensurate with the job that they're doing. In other words, they have to know how to do it. They have to have resources to draw upon, and I haven't seen where you're

really having that kind of instant response mode where you can -- where you're going to be able to do that.

If they are not as qualified to be in HACCP plans -- depending on the risks, a lot of these smaller plants are going to really provide very little risk. They're going to take products, maybe just from a box to a box that has been previously inspected and that the only chance they have to add any risk would be by cross contamination.

But if there is a risk, then, of course, the person there who is judging whether the risk has been met has to be sufficiently capable of doing it. The people that aren't maybe could go out into compliance. They could go out and watch and monitor from -- from the farm to the table.

I mean, I'm not trying to pinpoint exactly what should be done, but what we're trying to address here is like making a book review of what you're trying to do, and I haven't even seen the book. So, you know -- and the thrust is to give as much information as we can, and it needs to be evenhandedly applied, and if there are people in the system who don't want to do it or are overly aggressive in deciding whether something is right or wrong, that has to be addressed within the system, too. We haven't seen that along the line up to date.

At bigger plants, you know, it's much more personal in a small plant. I mean, you really know everything that's going on. I mean, you go down there, and you open the door the first thing in the morning, and you're the last one home, and when I

ran my own business, that was one of the reasons after 30 years when I'd been bought out and I'd been working for the company that bought me out, I decided I needed a change of life, was because I was working seven days a week, and in the larger companies, even though there are important people, they have more of them, and that's some of the things.

I guess I have other things I've said. I don't want to speak too long. I've been accused of doing that at times, and -- but as it comes along, now that I've documented myself, I'd like other opportunities to respond.

MR. SMITH: Well, Stan, you know, I've been in a lot of operations like yours, that you're describing. I think what's going to be important here that we need to teach and train our inspectors and veterinarians and supervisors is to be able to -- and I think we can do this, and many of them are extremely capable in identifying what is a critical health and safety hazard deficiency that's going on. What is direct product contamination, and if we have those situations, we need to be acting -- reacting to those.

I think what's important here on the SOPs though and in the HACCP plans is that there is a responsibility that the plant identify those and react to those first, and if they do, and if they do, we're not -- we have no action because the plan is being followed.

I know that in the small plant environment, just as you said, one person can't do all them. The -- you know, as we change --

I think empowering employees to be able to make decisions and to be able to react to those things would take some of the pressure off that one person, and so I think as we have to get our inspectors to -- to identify and react when we have these direct product and serious situations, that the employee has to be able to react to those also and not rely on one person, and if that one person's not there, then things don't get done.

So I think it's going to be a fundamental shift, and I think HACCP would probably drive both of us in that direction. We do realize that the appeal process is very important, and we will be emphasizing that and making that very clear that all plants have the right to appeal. It's in the regulations now. Nothing has changed on that, and if you don't get the immediate response at the next level, then go to the next level.

We are going to have technical expertise for our inspectors to be able to call at the area office, and from the area, will then be able to get either direct contact if the expertise lies in the region at this point, at least on day one, then those would be the people that would be getting back to them quickly. If not, we'll get it to Washington and get back on those cases.

So we do plan to have a rapid response because we know that that is -- that that's going to be important especially in the validation process. If we have a question about a time/temperature critical limit and our people really feel there is a hazard with that even though they have documentation to support that critical limit, then instead of taking the

immediate action which I think a lot of people are -- are leery of right now, the action would be to call the area office to get the science and technology because they're the experts that can really make that call unless it's very obvious. I mean, if somebody has 110 degree Fahrenheit cooking temperature for a frankfurter, I don't think we need to go to Washington to determine that's inadequate.

On the other hand, if we have a time/temperature with humidity that we're not quite sure about, the action is not to stop the plant. The action is to get the technical expertise involved in order to make that decision, and that is a lot of what we're developing along these lines.

So I agree with a lot of what you're saying, but I think the SOP and the HACCP plan itself will force everybody to look at what they're doing and who's empowered to act, especially -- especially in the sanitation arena, that if people see direct product contamination, they need to be able to stop and react to that and not wait for the supervisor or go chase somebody down, and say, I think something's happening out there.

I think we have to get people in the mode to be empowered to act immediately to handle that, and if that's going on, then that removes what the inspector has to do because the pro -- the program is being followed. So I think that's some of the -- it's new thinking for all of us.

MR. EMERLING: Just another comment. It would seem that there should be some benefits, you know, in the freedom to

operate as you go through for someone who has successfully done it, who has been verified that they're doing it, and you know, things like being able to operate at any given hour, 24 hours a day, seven days a week, subject to the oversight, not subject to overtime penalties or payments or whatever it would be.

And especially in businesses that are on quick reactions times, they are faced with a lot of instant demands. I know that NAMPA has members who export into the Caribbean and places like that where they can get a call at two in the afternoon and need to get it out that same day. Well, if they're hitting into their overtime problems and they haven't told somebody about them, they have problems, and they can't do it, and if a person wants to operate at some irregular or odd time for circumstances that are peculiar to that operation, your system doesn't allow it, and we hope that you'll take a look at that and do something about it.

As a final question just to you because as you mentioned to it about the person being in charge, what happens, what have you decided you're going to do if in a small plant -- because some of the plants I heard here only had four and ten people, and if they haven't a need for a HACCP plan, what are you going to do when that person designated isn't there and an inspector walks in and asks for that person in charge of the HACCP program, and they say he has either been sick or he's on vacation. He's in Washington or whatever the case may be. How are you going to address it?

MR. SMITH: Well, again, Stan, I think we've said as far as having that we want to a HACCP trained individual in the plant, I think everybody has to -- everybody cannot rely just on one person. Now, whether that -- you know, and so in the absence as long as somebody is familiar with the plan and can be operating, I mean, I don't think we're going to shut somebody down because for 15 minutes, the HACCP trained individual is not on site.

MR. BILLY: I need to -- hold on, now. I need to correct something. The proposal does not propose to require that the HACCP trained person be in the plant. The proposal requires that the HACCP trained person be available. It's up to the plant to decide how that person is available and what time frames. The proposal also specifies certain roles that that person needs to play in the course of the HACCP program, and again, there's flexibility there in terms of how the plant accomplishes that.

So I think there's flexibility there in terms of that situation. It's not a requirement that a HACCP trained person be present all the time in a plant.

Okay. I'd like to take a break for 15 minutes. Come back at 11:15.

(Whereupon, a break was taken from 10:53 a.m. until 11:22 a.m.)

MR. BILLY: I'd like to ask everyone to get seated so we can get started. I'd like some guidance from all of you in terms

of where we go from here. I think that the discussions after Mike's brief opening remarks have been very useful. There have been some specific concerns that we focused on, and hopefully, there is some clarification and better understanding, and that's important, and I don't want to diminish that or prevent that from continuing to occur.

We do have -- we did propose to talk about what's contained in a very brief way in this backgrounder on the reg reform package, and to talk about this in some -- a little more detail where we think it will provide some further insight in terms of examples of how existing regs are going to change, and existing requirements of various types.

I'd like reaction from you right now about whether this is sufficient and you folks get the picture and we can forego that, or it would be worthwhile to take ten minutes and go through this so that for those that haven't had a chance to look at it or they have questions about what's here, we can get those on the table as well.

So just give me a little bit of a reaction of what you would prefer to do in terms of continuing the dialogue. I've got about 12 or 13 people that want to speak, presumably on what has been talked about already or this morning or whatever. Should we just continue that process or shift to -- and have a little bit more on the reg reform package? Reactions? Speak up. Tell me what to do.

UNIDENTIFIED PERSON: Why don't we continue the dialogue?

MR. BILLY: These things shift. Any other -- all right. I think what I'm going to do then is continue the dialogue and work through these people, and then maybe after the lunch break, we can get into that -- that follow on presentation and discussion.

So the next person on my list is Jim Hodges.

MR. HODGES: Thank you, Mr. Billy. The -- some of the most troublesome conversations yesterday and today I think come from a lack of real understanding about the direction that the agency may be headed. On a philosophical basis, the -- the agency is clearly going in the right direction about how they will approach the HACCP portion of the -- of the proposal.

I will qualify that with -- with at least one or two caveats, and that is, philosophically, you're going in the right direction, but I hear the message of inspection in the plants being a modification of traditional inspection and not a fundamental change in the philosophy that's absolutely compatible with a HACCP program. I think that's been discussed by some of the previous speakers, and I'm not going to be redundant about that.

The thing that I think confuses at least me and maybe part of the audience is that the proposal has a variety of near-term mandates. It has microbiological testing, and by all accounts, I think most people would agree at least from the industry's point of view that those near-term initiatives and the microbiological testing requirements are a fundamental

continuation of our traditional inspection mode.

Now, if you're proposing to do those while at the same time you're proposing some fundamental philosophical shifts in the way the agency conducts its business, I think that puts us in a -- a little bit of a position of some -- being like a wish bone. We're pulled on one side and pulled on the other, and we're breaking in the middle, and that's a very, very difficult position for the industry to, you know, to cope with.

We hear continually that our problem is not so much that we're going to do a -- what I call a clean up of the regulatory -- of the rules, but we are also -- we would also encourage that that has to include the issues of policies and directives and memos and notices to the field because those in fact are operated just like they are -- just like they are regulations.

Those kinds of directives to the field clearly need at least in our opinion to be compatible with HACCP also. In most cases, they today are counterproductive to improvement and counterproductive to the way that we in the industry feel that the system should be going.

Examples of that is that when you talk about the layering issue which is the subject of today's meeting, it -- we can clean out all of the policies, directives, notices, and regulations, but unless we fundamentally change the way that the inspector operates in the plant, we still have a layering issue to deal with.

We also have a layering issue to deal with in terms -- in

terms of saying that we want to -- we want plants to be mandated to have a HACCP program in place which is a preventative system while at the same time saying that we're going to be measured in the ultimate end by some type of performance standard.

Now, that again at least in our opinion is an issue of conflict, redundancy, or layering, so you have to try to keep your focus on what -- what we believe is the agency's correct position. It's eloquently articulated by Mr. Taylor, he and Mr. Billy, but we need to -- we need to be -- to have some mechanism to set these issues about the near-term initiatives, microbiological standards, set those apart from what the philosophical bent is of putting HACCP into -- into the system.

If we don't do that, we're going to continue to have this confusing discussion about, well, which direction is the agency headed?

An example of that. If you look at your top to bottom review, there's a lot of very significant information in them. We talked a little bit about blueprints, and I don't mean to pick on that specifically, but that's just happens to be one example that pops to mind.

In the blueprint area, the options that you've laid out in the top to bottom review, many of those options talk about some type of disapproval by -- I mean, that's my word -- disapproval, submission to the area offices, evaluated by the IIC, and those kinds of things.

Fundamentally a problem. Fundamentally a problems in terms of how you -- of whether -- if you get rid of approvals and put that responsibility clearly on the plant, disapproval is tantamount to having an approval system. So we're only making very small, small changes toward a completely different system when I think you need to basically define that there is -- there is large differences that need to take place.

You can't -- if the inspector in the plant continue to have -- continues to operate in the mode he has where there -- where at least in my terminology, we have great difficulty separating the significant from the insignificant, then we're going to continue to key on what happens to the plant and what happens with the inspector's actions in the plant, not key on what makes it -- improvements in food safety.

MR. TAYLOR: Jim, let me just make a couple of comments. I want to the broad philosophical question of what is layering and are we -- do our proposals embody still layering, but before I do, just a couple of things.

One, just that I make this point generally for people who may not yet have read through the 600 pages of top to bottom team reports as Jim has done, but just be very clear that -- that those reports, and this is laid out briefly in the Federal Register announcement, that's the work product of groups of employees who were asked to array options and possibilities and provide analysis to feed into our consideration of a whole lot of issues involving how we do our job.

And the options are just that. On the specific issue of blueprints and do we need to have an approval system, again, I touched on that earlier. In the presentation this afternoon, Ralph Stafko will address directly what our current thinking is as embodied in the proposal that we plan to publish very soon.

The other just specific point I wanted to mention is that we agree with you that in reviewing existing rules to be compatible with HACCP, we have to go beyond the regulations themselves as codified in the JUST. We do have to look at directives and notices and other policy pronouncements that really are an extension of the current rules in terms of taking the command and control approach.

So we -- and again, the notice will be publishing soon describing our review of existing requirements says explicitly that included in this are those other means of delivering -- historical means of delivering directives in effect to the industry.

You talked about the notion that -- that by requiring or having proposed to require some approach to microbial testing that that in relationship to HACCP constituted layering, and I think -- maybe I misunderstood -- but I heard you -- I think I heard you say that if we're going towards performance standards, why would we, you know, be requiring something like microbial testing as opposed to simply enforcing performance standards.

I think that's a very good question. One of the things that

I think needs to be on the table in understanding what our proposals are about and in particular understanding our emphasis on performance standards is that we are not proposing and HACCP quite evidently is not about shifting to an absolute and total reliance on end product performance standards as the sole means of ensuring the safety of product.

And in fact, HACCP itself stands for the proposition that we also believe as a matter of what our regulatory framework is that we also ought to be addressing and defining in some manner what the industry's responsibility is for implementing appropriate process control. That's what HACCP is about.

And the way we've tried to craft this, the role in defining what the industry's responsibilities is with respect to process control is not to mandate what the controls are. It's not command and control with respect to what you do, but it is responsibility for maintaining some appropriate system of process control to meet the prescribed performance standards.

One of the issues, and I think this is largely tomorrow's topic, is in defining what's an appropriate approach to process control, what kind of achieves an appropriate standard as far as contemporary, modern, science-based process control, what role does a plant administered microbial testing program play, and we're going to have that conversation tomorrow.

But I suppose one could argue that if we're mandating HACCP and establishing performance standards, somehow that's layering. We don't view it that way obviously. We regard

HACCP and performance standards to be conceptually very linked because it stands for a regulatory philosophy that says the responsibility of the plant is to maintain process control, science-based process control that is adequate to achieve an acceptable level of food safety performance.

That's -- you know, in a nut shell what our philosophy is, and so we view it as an integrated regime, but this -- I mean, just people need to understand that it's not a pure -- in some senses, you could say it's not a pure performance standard approach in terms of end product standards. It is process control plus performance standards.

MR. HODGES: I -- just to follow up -- I would contend that your end product standards will be the primary measure by which a plant is judged in the end, based upon past history, and based upon the way that we currently operate unless we make a fundamental mind set shift in the way that we look at the system.

That end product testing, by definition, cannot -- cannot -- and let's take it out of the realm of just micro testing. I mean, end product testing in itself is a -- is not HACCP. It's not an efficient way to assure safety or quality or any other kinds of things. It is a means by which you can get some indicator or judgment that the process is in control, but it's certainly by no means a -- a system that we should key off.

But if it is codified in the regs as a standard, then that's what is -- that becomes the key.

MR. TAYLOR: And that's -- I mean, this is the question again that we have to be getting at tomorrow because I think we agree that end product testing is not an end in itself and can't be relied upon solely to ensure safe product, and that's why we all seem to be in pretty broad agreement that HACCP, a process control system that builds prevention into the system, has got to be the central framework and tool for ensuring safe food.

On the other hands, what we care about, what the public expects is not -- has to do with the food itself. It does have to do with whether the food is meeting an appropriate standard of safety, not the elegance of the process control system.

And so how do you have -- how do you incorporate, you know, in an overall regime that is based on HACCP and plant responsibility for process control, how do you build in some measure of accountability for achieving what in the end is important from a food safety and consumer protection standpoint which is acceptable level of performance with respect to the significant hazards potentially present in end product including harmful bacteria on raw product.

So it's -- that's what we're trying to get at is -- is how we have a system that works in an integrated way to achieve some acceptable outcome when it comes to food safety.

MR. BILLY: Angie?

MS. SIEMENS: Good morning. Angie Siemens from Oscar Mayer. I want to go back to an earlier point which happened quite --

quite often.

In terms of timing relative to implementation of HACCP and bringing inspectional changes and many of the layering changes that we're talking about, right now, I know in many of our plants as well as I think in small plants, we have products that fit your different categories. Many of them will fit the 12-month implementation. Many of them will fit the 18-month implementation.

It's difficult in our sense to say that we're going to say half of our plant is going to be implemented into HACCP in 12 months and the rest in 18. Are you prepared to bring, if I come to you and say in nine months after the final is available, we would like to go on to this new improved inspection system, get rid of the layering at that point, bring inspectors up to date to allow us to work into a HACCP system, provided the incentives are there for us to do that?

MR. TAYLOR: I'll say what comes to my mind. Bill would know the actual answer. We -- I've heard this question before, so I have a thought or two about it. I mean -- and I don't have a concrete answer, but the thoughts are these.

I mean, obviously, I mean, it is a very positive thing if companies want to move ahead and begin to implement HACCP and begin to do things that they think will improve the safety of their product, and we want to encourage that.

The question you raised gets, however, to a very complex logistical training, where are we in the process set of issues

that we to grapple with, and I think we ought to try to -- I mean, there ought to be time in this meeting to really focus on this in a thoughtful way and get some discussion because in order for us to have as a legal matter, for example, gotten out of the command and control mode, we've got to repeal some regulations. You can't do that overnight.

In order to inspect in the HACCP mode, we have to have trained inspectors, and that is, you know, is going to have to be done in some orderly careful way and can't -- it's going to be done in a very expeditious way, but it takes a certain amount of time.

So how do we mesh? I mean, that's the issue is how do we mesh, you know, our progress in making the changes internally we've got to make to be ready with the plant's ability and willingness to move ahead, and I think we need to talk about that because realistically, you can certainly imagine that, you know, as a practical matter for everybody, some kind of notion of phasing this in makes some sense instead of thinking that on a certain day, we're going to snap our fingers, and we'll be instantly transformed.

So I mean, it's a very important question, and as you can tell, I don't know the answer.

MS. SIEMENS: I just -- I have one more question or suggestion for after lunch. Because we don't have the regulatory reform proposal yet, I would encourage you to provide us some examples of specific regulations that you plan

on changing. It would help us in terms of some of the discussion if you'd be prepared to do that.

I seriously want you to consider timing on that because as you are well aware from the discussion yesterday, we have HACCP plans in all of our plants and processes, and if it is advantageous or an incentive to do so, we may request that of you to -- to go in even before the first implementation date on that. So I think you need to seriously consider that.

MR. SMITH: Okay. Again, I think that's an important comment that has to be discussed, and it's part of the regulation, and by bringing that up, I think, you know, we are struggling with that. We have 7,000 inspectors out there and 5,800 plants across the country, and to develop training packages to get the certain -- it's going to be -- it's quite a task ahead of us.

And so that's not a reason not to do it, but we have to balance that with how we are going to bring our people up. So there's not a good answer for that right now, but that's just another opportunity to think about.

MS. RICE: I have something I'd like to add just to my specific situation in that because we are a --

MR. BILLY: Could you identify yourself?

MS. RICE: Sorry. Kim Rice with Jimmy Dean Foods. Because we're a continuous operation, slaughter is 30 months, and ground fresh product is 12, and it doesn't make sense to have half of our continuous process.

MR. BILLY: There were quite a few comments about the process categories, and it's clear to us that we need to make some changes in terms of accommodating or dealing with that kind of situation.

So that's a good example where there will be some changes in what we -- what we ultimately come out with. Okay. Mike Donnelly.

MR. DONOVAN: Donovan.

MR. BILLY: Or Donovan. Sorry.

MR. DONOVAN: Thank you, Tom. I'm Mike Donovan with the Association of Technical and Supervisory Professionals, and I'm the national representative that is representing most of the people that are trying to lose their jobs here I guess when it comes with the people and the staffs in facilities, equipment, the chemical handbook, all the processing staff officers, processing supervisors out there, circuit supervisors.

And I guess one of my concerns is that we're starting to get muddled when I'm reading this information that we're getting in HACCP, and part of the getting rid of layering deals with the economic issues.

One of the things of getting rid of equipment approval, for instance. Our people do an admirable job of looking at equipment. There should be some type of self certification of people that are getting new equipment because some of this equipment gets very complex. The materials used in there could end up contaminating a product, and the product could get out

long before anybody would know what the problems were with that. So I think that's one issue that needs to be taken care of.

The other issue is that we have in the proposal, it says we're going to use the economic issues in PBIS, but I'm reading in all of these other things of getting rid of, you know, the chemical handbook, for instance. Not that there's any unscrupulous people out there, but I know when I was in the field, you would have chemical people walking in and saying there's nothing wrong with this chemical and having people use those particular chemicals, and it would not be in the handbook for one thing, and if it was, it was for inedible only, and the salesman's trying to get him to use it in his processing operations.

I have a real concern on that based on a lot of small plants. Where are they going to get the information? And the labeling issues. I'm a full advocate that we end up streamlining these avenues, but to do away with all the PQC programs, for instance, for identifying production controls, I think we need to make sure that there is some other alternative for the economic issues because that is still part of the federal meat inspection act and the poultry products inspection act.

But when we're talking about doing away with regulations here, most of those are dealing with the economic issues and not dealing with the health and safety issues that are what HACCP is supposed to be about.

I do have one other question for Bill when he was bringing up -- about the CCPs, and I think Katie and Kim over here were in that particular discussion, and the question that they asked is if we had a CCP, would they be forced to do it if it wasn't on their plan? My question is the reverse of that. If they have a CCP, are we going to design PBIS for their particular plant, include that CCP in the PBIS system?

MR. SMITH: What we're going to do is if we take a process -- the answer's yes, and the way you do that is -- is through your monitoring activity. It's going to identify that you need to monitor those CCPs for the process. It's not going to get specific as to whether that -- the addition of salt or the -- you know, there's going to be the kill step. The inspector is going to have to go in and identify from the plan what those CCPs are that constitute for that process, and then that's what will -- when we assign inspection tasks, to verify the CCP records, it would be all those records associated with those CCPs.

So it's completely different than how the inspection system guide is now structured, and it would take in that flexibility because it makes no judgments on what CCPs should or shouldn't be. It's what has been validated for that process in that plant, and then that is what is used to drive what the monitoring is.

MR. DONOVAN: Just to follow up. Are we -- is it going to be that some plants then are just going to look at what our

CCPs are, for instance, in our PBIS system and just pull out of there, and that's how they're going to set up their program without doing an analysis of their operation?

MR. SMITH: No. No. They have to meet the seven principles as defined and proposed in the regulation.

MR. BILLY: Okay. Now, I've got a Donnelly. It's a Nancy.

MS. DONLEY: I've been called Nancy Donovan though also, so I answer to anything. I'd just like to make a couple comments, pretty -- I guess they're really probably more general than anything else and just kind of speak from the consumer or the public perspective.

When I go into the grocery store -- first of all, I should identify myself. Nancy Donley from STOP, safe tables our priority. My local grocery stores advertise USDA inspected meat. They do not advertise USDA inspected paperwork.

If -- my point being that organoleptic inspection as we have it today must continue to be a part of the inspection process, that the hands on in the plant looking at the product must continue.

From a consumer's viewpoint, if that particular function were to be dropped, I think -- and it were to be known that inspectors were no longer having the ultimate responsibility of working with the system, with the product as it goes through the system, and monitoring for even some of the basic wholesome qualities that it would effect all your industries dramatically.

I personally wouldn't be buying any meat or poultry that I did not feel was being inspected, and it was just a paperwork inspection process. Perhaps if that had been in effect, my child might still be alive today because I would not have purchased any meat.

In addition to as far as with the inspection is that microbial inspection, as far as I'm just going to -- you know, I know this is going to be up for a future topic, but I would also like to suggest -- we believe that the inspection -- the sampling process itself should be done by the inspector, not by a plant employee, that there needs to be some sort of -- of guidelines as far as when in the day these should be done. I -- we think that one sample for any plant size is not necessarily -- definitely not enough.

This would also ease as far as the disparity that small plants feel, that they are -- that they are doing the same as required by the large companies.

Speaking of small businesses, I'd like to make a couple comments to what Mr. Emerling said before and that -- a couple of comments and responses here as far as that the small businesses are looking for due process and not exemptions.

They've been just -- have been invited to be just as much involved in this process as everybody else here, and there has been no effort as far as I can see to have excluded anybody, any sector, from participating in any of these discussions that you've had, and you've -- I want to commend FSIS for the

outreach that you've done.

I'm a small businessman. I have my own business, and I have made it my business to attend. I've been to at least four of these now. I personally went to the Kansas City specially called briefing for small businesses. It was an eye-opening experience there for me. I was not voted Miss Congeniality in the room after giving my -- my talk.

I can -- and please forgive me if this is redundant to some of you -- but as I've said, we've had ample opportunity to speak so that I'm saying some of the things I've said before. I can empathize and identify with small businesses' concerns. It's very scary to be put in the position of having your livelihood taken away from you, to have it threatened. I've been there.

January of 1993, both my husband and myself lost our jobs simultaneously. I worked in the apparel industry, and my husband worked in graphic designs. We worked for companies that refused to or could not keep pace with consumer demand for better quality at lower prices.

The industries continued. The companies didn't. My husband and I both felt that we -- frankly, we were scared. I didn't sleep nights. I shook a lot, got very scared, but I always knew that we had the basic tools, capabilities to continue on and to put a roof over our head. It might be a different roof. It might be a small roof, but we knew we could do it, and we did.

Six months later, my child was dead. My only child. My point being that the jobs can be replaced, but dead children are dead forever. That is why I'm very, very, very concerned with the attitude that small businesses in particular are taking with this. I heard some very, very strong comments when I was in Kansas City and some very, very, very strong concerns, and once again, I can empathize, but pathogens are not discriminatory when it comes to the bodies that they invade as well as the plants that they invade as well as the animals that they invade.

Small plants have got to be put into the same process at the same time that everybody else is, and the small plants need help, and I challenge their own industry to help them out. That's what you've got trade associations for and boards for is to help these people. Help your own.

It's just too important of when you have something where the health and livelihood of individuals are at stake, that the costs are just too high to cut anybody any slack in this particular case.

And so I'm just saying is that we all need to -- we all need to help each other out in this case, and I'm saying help your little brothers.

MR. EMERLING: You noted my remark on that. You know, I have absolute feelings, deep feelings for what happened to you, and I know everybody in this room has the same -- and we would not want it to happen -- or happen to you or to happen to

anybody else, but in just addressing beyond that to the comments that I made, I did not -- I said we did not want exemptions from this process.

We support the process 100 percent, absolutely, right to the end. What I said about due process was that we ask that there be a system in place that where the people who aren't performing, aren't doing, aren't living up to what you want us to do, and we want to do what you want to do -- want us to do, that they be directed out of the business, closed down, shut down, but all I want to make sure is that they have due process, that at least that it is not capricious and some kind of personal kind of situation that would cause that to happen, and that's what I meant in addressing that.

With respect to what small business is trying to do to help their people and the trade associations are, they've banded together into a HACCP alliance in order to try to teach people how to do that, and though I probably am not the right person to explain to you what that is and there are others here in the room that could including Devin Scott and Steve Krut, they could explain more, but they are -- have been working on this and trying to go forward, trying to make sure --

It's a little difficult because we don't really know all the things we need to address yet, but I can assure you from my viewpoint and from what I know they've told to me that they are on it 100 percent, and they're going to give it, not 100 percent, but whatever percentage infinitely it needs to make it

work, and I hope you -- we -- we are -- we know. We're consumers ourselves. We're just as concerned as you are, and I just hope that you understand how we're approaching it and what my -- what my thoughts were.

MS. DONLEY: It sounds then as if the -- this additional time needed for small businesses or the 36 month implementation program for small businesses is then -- it sounds like not necessary because the industry is taking care of that, and is it a case where industry is ready to say, hey, we can't all implement this at the same time table. There is no need for -- because of the HACCP alliance, there is no need to stretch it out for small businesses?

MR. EMERLING: Well, you know, I will let someone really go more into that, but I -- I think what you need to understand -- it -- because even FSIS doesn't know what it is going to do yet, can't even guarantee to them over here that they can implement it together because they're not sure they even have it all together, that what that time -- time frame would be, and for smaller plants that don't have the depth and -- and though they may have some sophistication, may not have the -- total resources to draw upon would probably would prefer to be piloting to make sure they are guaranteeing that they are sufficiently doing the job to assure the safety.

So there's a -- there's a time phase that was asked by small business in order to make sure they do the job right, not to delay or to postpone. Now, maybe Jim can answer more or

someone else, whoever you want to address the rest of what Nancy is asking.

MR. HANKES: As a -- Jim Hankes and I do represent the -- Association of Meat Processors, and my wife and I own a small meat processing plant. One of our big concerns is just, Nancy, is the communications. You know, a lot of the small plants do belong to our association. They belong to our national association, our American Association of Meat Processors, and we get as much information as we can through our associations, but let's face it, where we're at today, things move slow unfortunately.

The bureaucracy -- you know, it takes a long time to get this information. It seems like it takes longer to get it out into the countryside, into the small towns, the small communities, than it obviously does in with the large companies.

We do not have the staff of attorneys. We do not have the full-time quality assurance people or people, you know, in those positions because we're doing those jobs. In multiple cases, we're doing them ourselves, and so I think the extended time given to small business probably was looked at as a need to get this information and -- out into the countryside, out to these plants.

In our particular case, we're a state inspected plant. Now, we've got another level to go through, and this hasn't been discussed or anything, but we'd have to see what FSIS -- you know, they have to relay this information to the state programs

across the country, and then the state programs will have to get it to the plants that are state inspected.

There's another step, and the majority of us state inspected plants, our -- we are small businesses, and I know Stan was talking about numbers of small business being two and a half million dollars, we sell less than a million dollars worth of inspected meat products, and I know there's small mom and pop shops out there that may sell a quarter million dollars, you know, in this type of thing.

We want to do whatever we can to produce safe products, and I -- now is maybe not the time, but there's not too many business people here because I know in our particular case, I'm reporting back to them Sunday at our meeting, what went on this week and where do we go from here.

My plant, we slaughter. We process. We make about 100 different multi-ingredient products. We do catering. We have a retail store where we sell fresh frozen foods along with our smoked products. We're so diverse, it would blow many of the big companies away. I mean, we do a lot of things.

That does in a way make it more complicated. It makes it more difficult for us to manage, and this is why personally I'm here on a fact-finding mission to figure out how we can survive, you know, a competitive world. We may have to make 20 products instead of a 100 when this is all said and done. We may have to eliminate and rely on some of the larger companies for more of our products.

Whatever it takes, there is a group of us that are competitive and will be in business 10, 20, 30 years from now regardless, but we had -- in the whole stage of the process, there are some small companies out there that have been there for generations, and it's difficult at times for these people to change, and we want to get the information to these people the best we can, you know, between the government and our associations, and go from there and see what we can do to produce a safer product.

MR. BILLY: Steve, you're next, and maybe this is very germane to your area of interest.

MR. KRUT: A few hot spots I guess. You know, a few years back, there was an article that circulated around the country about how many regulations affected the production of a hamburger, and maybe it was a dozen years ago, and at that time, they identified over 38,000 individual regulations, federal regulations, state regulations affecting the production of one hamburger.

When I hear the discussion about layering and removing some things, I understand, you know, we've got so many things on the books, we don't even know how many books we've got any more, and I can appreciate when I hear Nancy say, I want to go in and buy inspected meat. I don't want to see that they did a lot of paperwork.

I think what we're heading for is a -- not necessarily a Simon-pure HACCP system. I think if you heard some of the

folks from the inspection ranks yesterday, there's a tremendous amount of mistrust -- on the part of a lot of the plant operators. There's an awful lot of mistrust on the part of inspection people as well that we've got a system that is abusive, that we've got people with swollen badges that don't know how to act. They're not human.

What we're looking at, and this is in trying to put it in a real world scenario, we have a system that now is so specification oriented that it is -- no one could actually keep up with it, but we have conflicts and challenges about what is correct and what is incorrect procedure in a plant about specifications, and then, again, as Michael Taylor indicated earlier, we've got all these policy memos and other directives that were never really formally promulgated. They just happen.

We've got inspectors in the field who have 20 and 30 years experience who have enforced this and said, well, we understand why we're doing it. We have people that say we need blueprints approved, and we say now, well, we may not have the approval.

Somebody has got to sign off somewhere, and this is what's fearful about the system, and so when we're starting to talk about what we're going to remove in extraneous regulations and rules, realize they're going to be -- this is going to be a partial step, that we're going to develop some HACCP, and we're going to develop some quasi presence in inspection as well.

Things like the carcass by carcass slaughter inspection, I think we're going to continue to see that, and we hope we do,

but there are going to be areas where we're all going to make adjustments. In the continuous inspection in processing, that is absolutely unnecessary in some situations. In some other cases, it's absolutely essential that it be continuous.

I think we've got to look at the present system and what frustrates everybody about it, so that when we're starting to look at how we want to phase in HACCP. Whether it comes about fully in a few years or many, many years down the road, we make that transformation will not happen until that mistrust is removed.

It's just a matter of fact, and I think we've got to look at what we need to do to remedy the problem in the present system, and I'm suggesting here that we do have an issue that's not even on the table under layering, and that's the appeals process that's always alluded to when there's a conflict.

You're appealing items dealing with specifications, and when you're talking about HACCP type appeals, you're talking about performance standards, exercise of common sense sometimes.

I can see without a device or mechanism or a process that is a workable appeal process, the situation will just get much, much worse in terms of conflict between the inspector, between the plant operator of who do you appeal it to and, you know, the present system just backs up its own, and follow this procedure, and you open yourself for intimidation.

The inspector will look back at the other side of the coin and say, well, we've got people that if we're not there,

they're going to play games. I don't have an answer, but I'm saying that as we move down this road toward implementing HACCP, it's not going to happen overnight. It won't happen -- and as Stan and Jim said, small plants are not looking for exemption from the safety to move toward HACCP. We want to be in a preventative mode as well.

But in -- in true light, we're going to see the need for more pilot projects in the small plant area, and I want to emphasize this. I was going to mention it later in the day, but there are processes where HACCP has been absolutely demonstrated to work just about flawlessly.

In a small plant environment, with multiple activities including slaughtering, processing, wholesaling, retailing, multiple products, limited amounts of those products, seasonal items, we have never actually tested this process, and one of the things we asked for at the scoping session was let us look at the results of the six pilot plant studies.

Only one of those was done in a true small plant environment, and with that in mind, USDA did the training, wrote the HACCP plan, did the verification, and essentially monitored the paperwork, and we came up with a cost $27,000 for one product in one plant that makes over 100 different products and has four or five different major processes including catering and slaughtering any everything else.

And I think before we make a wholesale switch to that system, we support HACCP strongly, but we need to make sure we

understand the cost and we understand the benefit to be received from it, and that's all small plants are saying. In that particular environment, let's make sure before we jump from one stone into the next stone in the creek, we're sure that stone's in place.

MR. BILLY: The -- we do plan to talk about that specific idea of pilots, focus on small plants this afternoon, so I think you'll support the ideas that we have on that.

I'd like to -- Joe?

MR. MAAS: I guess you're done pushing all your buttons on that? My name's Joe Maas. I have a small meat plant in Cincinnati, Ohio. My brothers and I have a small meat plant in Cincinnati, Ohio. I -- I have a couple of points, and I'll try and move through them quickly.

The first I'm responding to something Mike Taylor was talking about earlier regarding -- he asked, you know, how does everybody feel? Would you like to have prior approval or not to have prior approval? I'm going to be as careful as I can to not say that I'm representing small businesses in general although I associate personally with a lot of small business and talk with them frequently. I'm not -- I belong to several small business organizations, but I'm not in the hierarchy or framework of such.

I guess someone somewhere decided that HACCP is a quality control plan that's better than the one that I have, so I'm assuming that, you know, we decided that that's a fact, so then

the USDA, it would appear, is going to force me to have HACCP in my plant.

And so I've accepted everything else that USDA has -- has reined down upon me, and I've followed all this. I can only say that if you're going to do that, for myself personally, I would prefer that it would have prior approval, that the plan that I have would have in fact prior approval, that somebody said, yes, Joe, this is -- this is what we want you to have, and this will work.

Rather than, for myself, you know, putting together a plan -- you know, in my plant, I will be the person to train for the HACCP, so I'll put the plan together, and I'll assure you I'll do absolutely as good a job as anybody can do, but in any case, it's still at the discretion of the inspector as to whether it's good or bad, and I think maybe I have a little problem with that because I run into situations which then goes into the next subject with regards to some prior approvals of other things.

I run into situations where I have used the equipment branch and so forth here in Washington, you know, to get an inspector to lay off me because, you know, they -- they're looking at a piece of equipment as though there's a problem with it. I don't have a problem with it. The products that I see appear not to have any problems. I personally do occasional micro tests on my finished products. We do daily organoleptic tests on all my products.

So you know, there doesn't seem to be a problem, but the inspector has a problem with this piece of equipment. As it was mentioned earlier, you know, a lot of the equipment that's out there is very complex, and to leave it up to the local inspector who probably isn't trained to understand bearings, seals, and so forth, I have a bit of a concern with that.

Thanks very much. I'll just leave it at that.

MS. RICE: Can I just get something cleared? Kim Rice with Jimmy Dean Foods. This happened all day yesterday, too, where HACCP and quality kept getting shoved together, and I think it needs to be clarified that HACCP is not a quality assurance program. It's a food safety program, and others that have more experience with it can speak up at any point and tell me I'm wrong, but I think that needs to be clarified and separated out so that when we do have discussions about HACCP, we're talking about food safety programs, not quality programs.

MR. BILLY: We agree with that as well. To this point -- okay. Steve Donovan. Or Mike Donovan. Excuse me. Sorry.

MR. DONOVAN: All I was saying when I brought that issue was because of the papers seemed to start getting the quality issues mixed in with the safety issues, and that's what I was getting concerned about. It's the writings and everything else that has been coming out here was including both the quality issues and health safety, and that's what I was trying to bring out, too.

MR. BILLY: Dave.

MR. CARNEY: Dave Carney, National Joint Council. All of this talk inspection and everything brings to light a trip that you and I took last fall, Tom. Remember, I invited you to accompany me on some plant visits so we'd get you away from that fish mentality?

Well, we visited plants in three states, and we found that a lot of those plants already had self-imposed HACCP, and it ranged from excellent HACCP programs to programs that weren't worth the paper they were written on, and that's when we were really getting to the mega reg and the infancy of this, and I made a recommendation to you is that we take a sample from small, medium, and large plants, incorporate the plant profile and the PBIS that's there in with the existing HACCP program so that the inspector in that plant could get a feel for what HACCP will ultimately be as a reality.

Evidently, that recommendation made some sense because I never did hear anything back on it.

MR. BILLY: I think you're going to hear more about that kind of idea and how it fits into our scheme as we look forward later in the discussion, so it hasn't fallen into a hole. It's part of it.

MR. CARNEY: Now, don't forget the recommendation was for the purpose to save thousands of dollars, so we won't have to pilot test something all over again. I mean, the resources are already there.

MR. BILLY: Irwin. Hold on a second. Tom, is it on this

particular -- all right. I'll get you on the list.

MR. MUSKAT: Irwin Muskat, Jackback Foods. First, Nancy, I'd like to address something that you touched upon, and that was HACCP verification, and I gathered you alluded to the opinion that HACCP was verification was basically a check of paperwork.

Proper HACCP verification is far from that. If you're going to verify a HACCP program, what you basically have to do is take the paperwork, yes, but you have to go into the operation and verify the process that -- you are actually making an audit of the same -- in the same depth and of the same style that you're -- plant personnel are doing.

You're making sure that the process itself is in control by taking tests. If it means bacterial tests, then bacterial tests. If it means that you're checking on the hygiene of the employees or you're checking on good manufacturing practices, you're actually going out into the floor, and you're finding out, are they doing what they say they're doing. That's the check.

So, yes, we are sampling product. Yes, we are looking at product. Yes, we are testing product, and you can't do an audit unless you're going to do that. You do have to check the paperwork. that --

MS. DONLEY: Can I respond to that?

MR. MUSKAT: Sure.

MS. DONLEY: I agree with you a hundred percent, and that

was not -- that's not my point. My concern is just that it gets -- that -- my point was that we cannot drop the organoleptic inspection and rely strictly on the HACCP -- the HACCP proposal, that -- that both need -- organoleptic inspection needs to be a part of the entire inspection process.

Let me make it very, very clear. I'm very much in support of HACCP, very much in support of it. So, no, my point was just that we cannot drop the organoleptic inspection portion.

MR. MUSKAT: I understand where you're coming from, and I'll just make one more comment on organoleptic inspection. We have organoleptic inspection now, and I'm sorry, but you can't see bacteria. You have to test for bacteria. If you want to find out whether the food that you're serving and the food that you're selling is safe, you are not going to accomplish that in the manner that you want to get it accomplished with organoleptic testing or organoleptic inspection.

However, if somebody obviously sees something that's drastically wrong, organo -- by visual observation, naturally, you want to do something about it.

I'd also like to address a comment that you made, Mr. Taylor, and it was regarding HACCP and end item examination or end item inspection, and I'm not sure I got the right impression from what you said, but HACCP by its very nature in my opinion is almost mutually -- is almost mutually exclusive to end item acceptance.

And if you're talking about end item acceptance versus end

item verification of your process, the two don't live together, and I think that's the crux of the issue that many of us have with your approach or your department's approach or what we hear of your department's approach to HACCP.

If we're going to enforce end item examination and end item specifications and end item regulations, and they are going to start overriding the HACCP program, then you're going to defeat the HACCP program. The HACCP program by its nature is to reach a goal of food safety, but it reaches it through process control rather than end item acceptance.

I have one -- if you want to -- go ahead.

MR. TAYLOR: Again, I -- the observation I made which I think is very important and I think is consistent with what you're saying is that you can't achieve your food safety objective relying solely on end product testing to find problems, and that's why HACCP is the concept people seem to agree is necessary because it's designing preventive controls into the system to achieve the goal.

If this thing stops humming, I'll finish my observation or should I just keep going?

Again, tomorrow we're going to debate the issue of what role performance standards with respect to harmful bacteria might play in providing a measure of accountability for controlling and reducing harmful bacteria, and we proposed an approach that envisions finished product testing as a way of verifying whether over a period of time a process is being controlled

adequately to achieve some identified target for pathogen reduction which is different from what I think you were referring to as a -- I've lost the term you used. Product acceptance.

We didn't propose this testing as a means for deciding whether any particular lot was acceptable, but rather whether a process was being controlled adequately over time to achieve a target, and that's sort of concept is again what is in the proposal and presumably will be the focus of discussion tomorrow.

I guess I want to quibble with you on one point though which is that -- and let me put this in the form of question to you. I mean, HACCP addresses more than harmful bacteria. HACCP will address chemical residues, for example, and I suppose it's possible that a company might incorporate as part of their verification scheme some finished product testing on some basis, not presumably by lot, but might upon time to time choose to test finished product.

I know some companies do that for compliance with pesticide tolerances and food additive tolerances, and so forth. I mean, if you conduct that sort of testing in your plant and find a particular lot of product that contains a pesticide residue above a tolerance, in that particular case, would you regard that as a lot of product that needs to be disposed of in some what that complies with that tolerance?

MR. MUSKAT: I can't envision that we would have an end item

examination that would show something unfit for human consumption in any manner that would go out our door. I can't envision that we would even get to the point that we have a product that is out of specification that does not -- and specification, not meaning necessarily harmful to human health, but even at a much lower state than that. Something that's out of specification for our customers even for whatever their specifications might be for food safety, that would go to that customer.

It would be some other option as long as it was not a food health safety issue.

MR. LOCHNER: Can I ask a -- this is Jim Lochner. When you bring up your example of chemical residue, and I've struggled with this in my HACCP programs for fresh meat, if you look at the data from the national residue monitoring program, you would say that there's not sufficient violation basis surveys to sample, yet I haven't figured out a way other than sampling to verify that it's not there.

So it's kind of a dilemma. You can notify livestock producers, and they can -- you can have a notification, but there's no way around this. My opinion is that the national residue monitoring program suggests that chemical residues are not a sufficient problem, but I'd like some feedback from the agency on that.

MR. MUSKAT: Can I finish what I was going to say before we go into that? I had three points. Let me finish my third

point.

I think if we want to clarify HACCP, people should understand that almost everybody in this room is already employing HACCP as a program, and everybody's allegations that HACCP is not a quality program is not really true. HACCP has nothing to do -- the principles of HACCP do not necessarily -- are not necessarily relegated to food safety. We all employ HACCP programs in our day-to-day lives, in our operations for quality of product. We have a dual HACCP program. One is quality, and one is safety. Hazards do not by themselves as a dictionary definition have anything to do with pathogens or food safety or health safety. Hazards can be an economic hazard just as well as it can be a health hazard, and therefore, the programs that almost every meat packer in the United States or meat processor in the United States currently employ employs a HACCP type concept in that they're checking their raw material coming in the door to make sure it meets the specifications for what they paid for, and then they're checking it further down stream to make sure that they have yields and cost analysis and all of those steps.

They are taking their critical control points, and they are measuring hazards, economic hazards at those critical control points to make certain that their program and their cost controls are in fact working, and therefore, you can have a quality program under a HACCP program.

I'm not -- I don't want to confuse the issue here. I know

we're here for food safety, but if you make it simplistic enough so that some of the smaller packers who have difficulty with this process and this program understand that they're probably in a HACCP program now and don't even realize it, it could be made a lot simpler.

MR. BILLY: -- we're going to come back to that.

MR. TAYLOR: Irwin, I think I understand your point that the kind of the concepts that are embodied in HACCP can be applied to building preventive measures into systems to deal with other, you know, non-safety concerns as well and that many plants are already doing that.

I mean, as a regulatory matter, what we proposed was that companies operate HACCP plans to deal with food safety hazards, and I think barring some radical turn in the comments we've received so far, I mean, we intend to keep it that way.

I guess Jim asked a specific question about the current residue monitoring program, what that says about the state of play and our level of assurance, and I'll ask Pat to make a comment.

MS. STOLFA: Pat Stolfa, FSIS. Jim, I think you put an important issue on the table. We have begun a process of applying quantitative risk assessment principles to our residue data of the past several years to determine whether or not the monitoring programs as we have maintained them for quite a few years now should we continue in that form, or whether we ought to change the form of what we do in the residue area.

And I think that in terms of -- we have been thinking, too, about the issue of how verification might be accomplished by plants. If -- if slaughtering plants were to take on some responsibility for part of the assuring that their products did not contain chemical residues, and I think that in addition to testing, it occurs to us that -- that certain producer groups have in fact come forward with residue avoidance kinds of programs that -- that -- that producers might undertake, and another type of verification other than testing that slaughter plants might be able to do would be to go out and see if in fact the residue avoidance program was in fact being followed as it was described in -- in some of these programs which we think are quite detailed and have some history of providing assurance.

So that's one other approach that we thought of.

MR. BILLY: Dane.

MR. BERNARD: Dane Bernard, National Food Processors Association. Did I interrupt -- okay. I'm never at a loss for things to talk about as usual.

On the last topic, the residue program, I think the pleasure we had in conducting a HACCP workshop at Texas A&M with a number of FSIS personnel involved, that was one of the topics of the day. The hazard analysis which is principle one if you go through that and you're a buyer of animals, and the residue data says there isn't any problem, any significant problem, then by having gone through the analysis which is what HACCP

does for you, it says in my HACCP plan in my operation that's not a significant risk factor.

It's not because the residue program has been effective. With the agency, as you properly said, has to do is decide whether the residue program continues as is or gets modified, but as a buyer of animals to turn into food, the data tells me that that's not a significant risk factor, and you've gone through the hazard analysis step to get to that.

Let me back up to where we started which is layering on and a comment that I made earlier and something else that Jim did that just set up a comment perfectly that I want to reinforce.

When he called everybody's attention, I think everybody looked up to this little area up here, and he commented that we ought to cover the water pitchers as you might have to do in a plant with that kind of a problem. It brings exactly to the point of what we want to effect change-wise in the plants.

To reenforce HACCP, the actions of the inspectors must convey a clear, simple message to the people in the plant that critical control points are in fact critical control points, and that how we react to deviations from critical control points is going to be definitely different than how we react to other things which may not be so important.

That does not mean we don't react to peeling paint or rust. What that says is the way we react to those situations must be distinctly different than the way we react to deviations at critical control points. Otherwise, the message gets diluted,

and that's what we have now.

If we, for example, made the penalty for every crime in society a mandatory five-year jail sentence, we'd probably have less jay-walking, but it wouldn't provide the proper incentive not to go out and commit serious crimes.

The same -- that philosophy must be carried over into the actions that we impose on plants such that when we say we're going to do HACCP and we set a critical control point, the way we react to that in terms of the inspection process has got to be different and distinct from everything else, and that has got to be a very clear message.

Also in terms of layering, as we go through everything else that the agency does, it should go under a microscope for a number of reasons. Language. When we say critical control point, that must relate specifically to what's going to come out of a hazard analysis and be in a HACCP plan. There can be no other critical control points. We'll call them something else, but you've got to -- you got to get the language clean.

When we talk about hazards, the dictionary may define hazard very broadly, but the national advisory committee and by adopting their position, both FDA and USDA have defined hazard very clearly in terms of HACCP as a safety oriented definition. May cause a product to be unsafe for consumption. That's the definition we've got to stick with. So as you go through these reviews, take a look not only at the activity but the language and the reaction to discrepancies from a program in

terms of reinforcement of HACCP. Thank you.

MR. BILLY: Caroline, you have the last word.

MS. SMITH DEWAAL: Hi. Unlike those who it took two hours to get to the microphone yesterday, and they forgot their question, I just add on to the list. I -- I have about three things, and I will try to be very brief.

The first thing, I think that we've heard a lot from industry this morning on the issue of layering, and that's appropriate because it's an industry issue. We are at the beginning of a process of fundamental change here, and we -- consumer groups don't oppose the elimination of duplicative or unnecessary regulations, but don't strip away existing food safety protections until we know that the HACCP system is going to work to offer the same protection.

And I -- we really need to -- I've heard a couple of references this morning from Kim Rice and Jim Hodges to what are you going to do about layering? Well, layering is appropriate. Layering is protective. Layering offers the consumer the assurance that during this transition time, there will be appropriate food safety protections in place all the way along, and if -- I will -- I will oppose the administration any effort they make to start stripping away those needed food safety protections before we really do have proof that HACCP works.

My second point is on the validation issue. When Bill Smith talked about validation, it sounds a lot like a check list, and

I know the acting undersecretary said it's not a check list, but I keep going back to this -- this problem that it sounds different when different people in the agency talk about it.

I don't believe that what you are talking about in terms of that day one going in and making sure they've -- they've done everything they're supposed to. That's not validation. That -- if you don't want to call it approval because the industry doesn't like that, don't call it approval, but don't call it validation because validation in my mind and I've checked with a few other HACCP -- well, not other. I've checked with some real HACCP experts. Validation is a different process, and I think the agency needs to come up with another word for that because that's my stumbling block.

Words here are important, and validation means to me that you have -- that you have identified all the hazards and all the appropriate critical control points and that you have verified them in some way using hopefully microbial testing or some other testing that will assure that the process actually words as it's designed.

Validation is not going in and making sure that they've got something on a check list that complies with everything in the rule because that -- they may have -- they may have done all that, and it still may not work.

The last question, and this is a question I have -- I don't -- actually, just my final point on that to Bill Smith is that -- don't say that -- or I guess I really have a problem with you

saying that, well, once you've gone in and done that initial quote, unquote, validation, then you will remove the underlying food safety functions because if that's all you're doing, I am not confident that that system -- I'm not confident that that HACCP system that you have supposedly validated works.

So you need a better system in place before you start stripping away the underlying food safety protection.

My last question -- actually, I think it was raised by an example Jim Lochner had about rust on the ceiling. The -- my question to you, Bill, if you have rust on the ceiling but it's not identified as a critical control point, but nonetheless, that rust, a big piece of that rust falls into your product, it's not a violation of your HACCP plan. What happens? Is the -- is the inspector empowered or is the inspector going to act to remove that product from the marketplace?

MR. SMITH: Okay. Well, that -- that last one's very easy because it's a failure of the sanitation operation procedure, the SOP, because that's direct product contamination as you described.

Inspectors will be allowed and be empowered to write those situations up and bring those to the attention of plant management, and we're -- they're going to do that.

MR. BILLY: Bill, you need to be more clear I think. Those situations, you mean rust on the ceiling or rust --

MR. SMITH: In a situation where it fell into the product is a direct product contamination situation. The sanitation

operating -- the SOP must address that, and we expect that the plant in a direct product contamination situation would react, and if they don't, then we will use our full authorities of official control action, retention, or rejection, and as I said yesterday, that repeated direct product contamination situations will be the basis for which we will go to suspension and start administrative case file and bring compliance in.

That's very different than what we're doing today. So -- so we take that extremely serious. The same thing, the enforcement as proposed in the HACCP plan right now is failure at that point and suspension.

Now, if it's just up there, and it's not falling in the product, it is still going to be documented and given to the plant. It's just as we said -- as Dane brought up, it does not have the same seriousness at that point in time. It's not that it can be ignored. It's not that it can just -- that we're going to walk away.

It is that it will be identified, and we want people to react to that.

MS. SMITH DEWAAL: Let me just make sure I'm hearing you, that what I'm hearing you say is what you're actually saying. Are you saying that even compliance -- if a company complies 100 percent with their HACCP plan, but they're still producing -- for some reason, something happens, and they're producing a hazardous product, FSIS can get in there and act to get that hazardous product from reaching the market.

MR. SMITH: Absolutely.

MS. SMITH DEWAAL: Okay. So --

MR. SMITH: Absolutely.

MS. SMITH DEWAAL: -- compliance with the HACCP plan alone isn't going to prevent companies or protect companies from having something else happen that would --

MR. SMITH: Right.

MS. SMITH DEWAAL: Okay.

MR. SMITH: We will react to any direct product contamination, adulteration instance that we come across, and we will take all our authorities and use that. I don't -- you have a valid comment about validation, the wording, and we would need to go back and look at that, but the activity, the activity is designed to ensure that hazard analysis has been done, and that -- in any process of hazard analysis, that is a full look at what chemical, physical, or microbiological hazards you could have, that the critical control point is established to control those, that a critical limit then will assure that they are controlled at that point, and if there's monitoring activity and records kept.

That is not a check list operation. That is an in-depth analysis by the plants to go through those steps, and it -- and when the inspector would go to do whatever we want to call that activity, that that is more than just a check list that I have this, this, and this. That is that hazards have been identified. The critical control points have been identified

to control those hazards.

What we're not going to do is have the inspector say this is the critical control point to control that hazard. It would be the reverse is the hazard has been identified, and what critical control point is in this program controlling that hazard, but that is not any obligation of our responsibilities.

So cooking temperatures, right now we have 145 degrees instantaneous and -- in several time/temperature combinations for roast beef. However, if somebody comes in with an alternative to that time/temperature but has the science to establish, and that's what we'd want the inspector to look for, that that is on record for that critical limit, that some kind of scientific backing is there, is evidence that that is a valid critical limit.

MS. SMITH DEWAAL: -- make very sure that that scientific backing includes microbial sampling for the hazards that you're controlling for.

MR. BILLY: I think I'm going to give Mike the last word.

MR. TAYLOR: I just want to try to confuse the language here a little bit more if I can and offer a way to think about this very critical issue of validation and what our role will be.

You know, when we -- when day one arrives, the date by which any particular plant is legally obligated to operated a HACCP plan, we're going to be rather serious about seeing to it that companies have in fact got in place on that day a HACCP plan that meets the basic requirements of the regulation.

One of which, obviously, as one of the principles of HACCP will be that that company has validated its plan. I mean, the real validation obligation is the company's obligation, and the thing that an inspector is going to be asked to do first, almost literally if not actually day one, but is to go through and see that they've got a plan, that they've validated it, that they've done the things that they're obligated to do under HACCP.

And that inspectional activity is different from additional inspectional activity that we might undertake later that we've been describing as validation, but maybe what we -- we ought to be using some other term because really our role at that stage is to verify their validation which might involve us really digging deep into the science, but it's the plant's obligation to validate it, and we will have inspectional activity aimed at really verifying that they've done that as well as activity to verify that they're carrying the plan out in practice appropriately.

So we maybe do need to refine our language a bit and not be misleading about where the fundamental obligation for validation HACCP plans lies which is with the plant.

MR. BILLY: Okay. I know there's others. I've got several more on the list, and any that I've missed, we'll add right after lunch. It's just before 1:00. I'd like to resume at 2:00.

(Whereupon, lunch break was taken from 12:52 p.m. until 2:18

p.m.)

MR. BILLY: I'd like to ask everyone to be seated, please. Okay. I'd like to get started again. I -- here's what I'd like to do. I have several names left on the list. I'm going to in a moment run through them, and the question I'm going to ask is whether any of the people that remain on the list at this point feel they would like whatever point or comments they wish to before we actually talk about the reg reform package.

If it's more relevant to this morning's discussion, or you know, another way to look at is whether they'll keep until after we have this follow on discussion or not. The choice is yours, but I'm not going to add any more names then until after we -- after we finish the presentation.

So Tara?

MS. KINDRED: Yes. Tari.

MR. BILLY: Tari. Sorry. Okay. And Lou Gast. He passed. Okay. What is it? All right. Rosemary?

MS. MACKLOW: Yes.

MR. BILLY: You want to be -- Tom Devine? Yes? Marsha? Okay. Okay. And Lee Jan?

MR. JAN: Yes.

MR. BILLY: Okay. And Marty Holmes? Pardon me?

MR. HOLMES: Pass.

MR. BILLY: Pass it? Okay. Okay. Tari.

MS. KINDRED: I'm Tari Kindred -- as a federal veterinarian, not FSIS. The National Association of Federal Veterinarians as

you know, Mr. Taylor, strongly support your HACCP initiative. Our only concern is how it's implemented. We're very supportive of the effort.

You did make a request earlier this morning about 9:15, and I'd like to briefly respond to that. You asked about comments related to what we currently do under inspection that work versus those that don't work. We think a lot of things that are currently done under inspection certainly can be changed and modified very productively and fit under the HACCP program.

Traditionally, we've had a very strong preventive system for approximately 90 years. Unfortunately, there have been some omissions in what's covered by the current system, but we think it has been an effective preventive system in many ways, in that the whole premise of the system initially was designed to prevent some public health problems by removing unhealthy tissues from unhealthy animals from the food supply.

For example, under the current system, tumors and systemic infectious conditions are being removed through ante-mortem and post-mortem inspection. We do think that that's an important function. In addition, we have had this inspection system in place which has screened out basically unhealthy animals from the food supply.

Many things that are of great public health concern are not known. For example, we did not know about O-15787 or camphylobactor or other things in 1980. The picture is constantly changing as we gain new knowledge.

So one concern we have is if we do away with continuous inspection of certain animal categories, what may get through the system. We also recognize that we have different populations of animals that we're looking at. Some are young uniformly healthy populations of animals. Those present a different challenge than old -- well, I guess you would say older animals with higher prevalence of disease conditions, so we'd like to see that addressed in what we're doing, and you may already have that in mind. We simply haven't addressed the issue here.

In addition, we did want to point out that slaughter and processing systems present different challenges and must be handled differently, and I think it's very readily obvious how HACCP can be applied very quickly to the processing systems. We think it's a little sketchier in terms of slaughter inspection.

Traditionally, in in-plant slaughter inspection, we've done many things besides look for ante-mortem and post-mortem pathology and screen it out of the population. We've looked at sanitation concerns both coming from lesions on those animals, organisms coming out of the digestive tract that can contaminate product, as well as environmental concerns.

And we know that most of those are readily amenable to putting them under the HACCP system. So we see a lot of things that work well under HACCP. Our major concern is basically carcass inspection in some form. So we would be curious to

know how you intend to address that.

MR. TAYLOR: Let me say a couple of things. That may be -- that's an issue that there's wide interest in, and maybe there would be others who would want to react or comment on what you've said and what I will say.

Now, I agree with your premise that the current system of inspection does contribute to prevention and contributes to food safety in very substantial ways, and you mentioned some specific examples of conditions that are addressed by the carcass-by-carcass system and that again are important for food safety as well as for meeting other consumer expectations.

And we -- again, as I said earlier, envision pursuant to the statutory mandate that exists today as well as because it's important to achieve these objectives, some form of carcass-by-carcass examination continuing in a HACCP environment.

And again, as you know and we've mentioned, there's a lot of very critical thinking being done within the agency, much of which is reflected in the top to bottom review report on in-plant inspection roles concerning the manner of conducting this examination, and one of the possibilities, obviously, is to vary the intensity and manner of the examination on a risk basis, taking into account what's known about the health condition of certain categories of animals.

So we -- you know, we're working on these issues. I think one of the -- you know, one of the issues that needs to get focused on and sorted out, and it may be it lies is logically

under the layering banner as any banner is -- is specifically the issue of the interface between a plant HACCP plan in a slaughter operation and the FSIS carcass-by-carcass examination which is a complicated question and even more complicated than with respect to HACCP's application, for example, in a processing plant where you have a HACCP plan for a process that involves a kill step and some very specific well -- you know, well understood and identified and sort of crisply verified control points, critical controls.

In slaughter, we -- we are breaking new ground really in terms of how to -- the application of HACCP, at least in comparison with the environments in which HACCP has -- you know, the decades of experience, and in particular, we -- you know, we've got to figure out sort of where the safety related aspects that are covered by HACCP, and clearly, we will be inspecting, you know, in kind of the mode that we've been discussing here today with respect to our oversight of HACCP generally.

How do those control points and our inspection there, how does that interact with our -- you know, with the carcass-by-carcass system? I mean, that's -- you know, that gets at the heart of the issue of how, you know, we will manage inspection and HACCP oriented plants.

And it's something we're grappling with. It's something, you know, we're in the course of our -- our review of existing regulations, we specifically raised this question, and we'll be

inviting comments through that Federal Register process on how -- what that interface should be. I'd certainly welcome any top of the head observations from others around the table, but it's a -- you know, it's a gut issue we're working on.

MS. KINDRED: Well, thank you. We realize it's a complex issue, and we appreciate your response. Thanks.

MR. TAYLOR: Okay. Thank you, Kari. Dane, you've had something to say on every other issue. Please don't be -- I was just kidding.

MR. BILLY: Rosemary.

MS. MACKLOW: Mine is just a sort of a general comment. I can go on for a long time, but I'll try not to. When I got this in February, I knew we were in something big. I'd never seen a package this thick from FSIS before.

What it really is and what we're grappling with here yesterday, today, and for the next several days, it's a paradine shift. It's a cultural shift, and it's a generational shift, and it concerns me greatly that we may shift the written document, but the people on all sides of the issue will trail far behind.

And there are lots of people involved in this. There are your people. There are the industry people, and there is the consumer out there that want the level of confidence. So as we struggle with all of this, I urge that we not try to meet some artificial deadline that says we've got to do it by such and such a date, that we -- we look at the various pieces that go

in because quite frankly, some of its easier than others.

And I have enormous respect that you yourself and Mike Taylor did a lot of this for the fish industry, but I got to remind you you started from a whole different place. They didn't already have a body of codes of federal regulations and nearly 10,000 employees of an agency out there. You didn't have to make those kinds of cultural shifts that this industry will have to make in order to meet the future.

So while that is a highly commendable, historical, and institutional pattern, it doesn't necessarily fit the dimensions of what we've got to accomplish in this industry in order to face the future.

I would point to you that if you've got companies that are making like products, and I know lots of them and they're relatively small companies, you take one of Dave Carney's inspectors, and he goes to company A and he validates their process. He'll go to company B and he'll say, well, yours doesn't validate because it doesn't meet -- match company A's even though they may make the same product because he is culturally attuned to the fact that everybody does the same thing.

That's a huge hurdle to get over. Tough for his inspector. It's tough for the companies. They may think that they meet the HACCP requirements by simply patterning on each other, and that may not be true because they have a different space or just minor differences for how they do things, and their

control points may be different.

I am concerned about the most vulnerable firms in this process, and they are the ones who are still trying to remember what HACCP stands for. They're not into the acronym yet. There are people out there who don't know what it means yet, and even if they can put the words to it, they don't understand what the foundation of it is, and you've got inspectors that are in the same position that may surprise you to find that out.

They all have to come up to speed. We aren't going to do it very quickly. It's going to take time, hard as we may all work, and that is of great concern also.

I, you know, would suggest to you that there are some things that we can do. We can do them very expeditiously. We can do them next week if you want. You've got firms in this room who already have substantial HACCP programs that are way beyond some of your wildest dreams, and maybe they should be given an opportunity to move aggressively forward and burn the trail for a lot of other people behind them.

And maybe that step process is a way to approach this. We can learn from our past on that. Not everybody went for TQCs, and there were reasons for that, and there were failures in that system, but maybe if we write the book right for the future, you can go forward in that score.

I would suggest to you -- and this is nasty of me, and I'm sorry. I shouldn't say this -- but you know, if you'd moved on

the petition I sent you guys a year ago on lockers, we wouldn't have to talk about that issue today or any future time, but it got shoved aside into a thing called regulatory reform.

The agency needs to learn to be more responsive to making those operating changes, whether it's something you're going to phase out all together or whether it's something you can do. We don't need fancy metal lockers on legs and so on in locker rooms. We can do with bins in some companies where they don't really change clothes. They simply put their purse away and put a gown on to go to work.

That's something that could have been done, and it disappoints me, and it doesn't speak well for the agency making really big change when it isn't capable of making small changes. We can talk about that all afternoon, but I'm sure you don't want to.

I'll rest a moment. Thank you.

MR. BILLY: Marsha. Oh, I'm sorry. That's right. Lee.

MR. JAN: I'm Lee Jan, National Association of State Meat and Food Inspection Directors. This morning, we heard several people say regarding the role of the inspector, HACCP, and about organoleptic continuous inspection, and one of the later comments right before lunch really made me think I need to say something.

Caroline's comment about the rust falling from -- on the product and asking Mr. Smith if the inspector had the ability to do anything about that under HACCP, and of course, the

answer was appropriate, but to me, that seems to be building a foundation to argue for continuous inspection, and with today's interpretation of continuous inspection, that means daily inspection.

And I don't believe daily inspection in processing plants -- I think that's something that is one of the failures -- if there is a failure in the system, that's one of the things that contributes to that because the term used earlier or yesterday, barn blindness. Inspectors can get barn blindness just like the plants can.

If you give a -- the plant the authority or say, okay, you have to do standard -- or standard operating procedures for sanitation and HACCP and those things, for those to work effectively, it's my strong belief that the inspector cannot be in that plant every day because what's going to happen is what see happening today.

The plant -- or plant employees will notice that the inspector didn't say something about something, whether it be barn blindness or whether just an oversight, or maybe the inspector was waiting to see, give the plant time to do something, but for whatever reason, if the inspector didn't identify the rust, then the plant says, well, that must be okay because they didn't say it was wrong. It must be okay.

And I'm afraid that if the inspectors are in the plant every day like they are now, we're not going to have -- give a chance for SOPs and HACCP to work the way it's supposed to work. We

still need to have organoleptic tests. Don't get -- I mean, inspection. I mean, that -- I'm not saying that we don't need that at all because we do.

And I think we need it on some relatively frequent basis. Whether it's once a week or whatever it be, and that would depend on the situation, but we still need that, but by getting the inspector out of the plant, it gives them a chance to see more plants, number one, get -- and get a broader view of what is out there, gives them a chance to see that subtle change or that change that's happening slowly doesn't sneak up him, and it gives the plant the responsibility or makes they rely on their plans.

But the plans do have to be effective, and they have to be applied effectively by the plant, but if we keep an inspector in there every day because it's working, I think that's going to be flying in the face of what we're trying to do with this thing. So we need to have them both, but we definitely need to get the inspectors out of the plants on a daily basis, out of the processing plants. Thank you.

MR. BILLY: Okay. I'm going to now have Ralph Stafko talk about the reg reform package -- oh, sorry. Tom Devine. I'm sorry, Tom.

MR. DEVINE: I have a couple of questions, but I did want to give a differing view to the last point that was made that plants will assume more responsibility if inspectors aren't there.

I think one of the real advantages of HACCP is that it pushes the industry to assume more responsibilities and have less dependence on -- things are all right if the USDA inspector hasn't cited that for something. The idea though that the way to get plants to be more responsible is for the inspectors not to be there is a very difficult concept to swallow, and it's going to be extremely difficult to sell to a public that's skittish about food safety.

It's like saying that children will grow up faster if their parents desert them. Well, they probably will, but there's liable to be some real disaster in the interim, and this industry doesn't need any more of that.

From listening to this morning's discussion, I realized there were -- there were four questions to pose to you all that I previously had thought there were answers to, and maybe it's just I'm in the process of reaffirming this.

The first is if you all could summarize FSIS's definition of validation including how that is different from approval. The more I listened, the more confused I got this morning.

The second is what are the criteria for inspectors to validate a HACCP process? Not just in terms of the seven principles, but vis-a-vis compliance with USDA's ongoing regulations which everyone's -- still are in existence when the validation occurs.

Third, do USDA's ongoing regulations still have the force of law if they conflict with a validated HACCP plan? And fourth,

what enforcement authority if any will inspectors lose if they detect violations of ongoing regulations?

MR. SMITH: I'll try and address most of that. I don't want to get -- if we put validation aside for the second, and we talk about the activity that we're talking about here, we would -- we want inspectors to go in and see that a hazard analysis has been done.

So for that particular process that's being done in the plant, we want to see that the plant has taken an active role to identify the microbiological, chemical, and physical hazards associated with that process.

We want to see evidence that that has taken place. We want to see then that critical control points have been established to control those hazards, and so for every hazard identified, we are going to be looking for a control to address that hazard, and that would be the critical control point.

Part of a critical control point is a critical limit which establishes the control. What is the factor at that point, the critical limit, when -- if it's sails that you have unsafe product. Many of our regulations today could serve -- could serve as a critical limit. The 160 degrees in poultry comes to mind. The 145 instantaneous of the time/ temperature in roast beef comes to mind. The patty docket and those time/temperature relationships come to mind.

The -- the actions when we do not mix raw and cooked, and the things that are in the regulations could be used as critical

limits in those situations, so as far as the ongoing regulations, they can be, and I -- and some plants will use those as their critical limits.

We are also going to be looking then -- the inspector is going to be looking at once a critical control point and that critical limit has been established that there is monitoring activity identified to monitor that critical control point, that there is going to be records available to -- that state that that monitoring activity is going on, that when a critical limit and a critical control point is not met, that they -- we will expect to see evidence that there is going to be corrective action that is taking place. Who's going to take that corrective action in the company? How is that going to be documented? How is that going to be -- you know, whether we're going through processing authorities.

There's going to have to be a mechanism in that plant to identify how they would handle corrective action, and last, then plant verification activities which means, for any given process that all those pieces are looked at before a product is shipped out, the monitoring, any micro associated testing, and not just microbiological but if there's metal detection, any chemical testing that relates to those critical control points has been completed, and that somebody has made that assessment that all those things are done before that product goes out the door.

Those are the things that we're going to be looking for as

part of that activity of determining whether we have a valid HACCP plan at least to start up under the proposed rule. Those are the things we would expect inspectors to be doing.

And therefore, if current regulations are used as critical limits, then they would meet -- then of course, we're going to be enforcing current regulation. If we have critical limits that have been scientifically supported that are equal to a lot of those regulations, then we're saying that the company can go ahead and use those.

So just as a case in point, if somebody came up with a time/temperature for poultry, let's say -- I don't know, just pulling it out of the air, 152 degrees, and they hold that for 17 minutes at 90 percent humidity and has the scientific evidence to say that that results in a -- reduction of salmonella, which is a lot of what the current 160 was built off of, you have an equal to the requirement we have.

And we're just saying that if we have that kind of information and documentation that supports, that we -- then in that case, that would become the critical limit that we verify in the plant instead of the regulatory 160 degree because they are equal to. They are equal or equivalent requirements, and I believe that's the wording that we use in the proposal, that if it's equivalent to, that allows the industry to innovate as long as they're equivalent to.

And so that's how we would see this operating under that activity that we've called validation up to this point, but the

activity where the inspector goes in and makes an assessment about the validity of that plan.

MR. DEVINE: So I heard an answer to one of these questions. In making the validation judgment, USDA's regs no longer will be controlling. They can if a plant opts to use them, but they won't have the force of law any more. If --

MR. SMITH: They'll be equivalent to -- and the proposal in and by itself and a regulation makes it subject to the law. The whole proposal is based in regulation, and we said we would suspend operation, a regulatory action, if those are not met, so --

MR. DEVINE: So if they've got a study -- if they have a study, they can do it -- they can cook to 150 degrees instead of 160 degrees despite a conflicting USDA regulation. As long as you all review that study and agree that it was --

MR. SMITH: That's it's equivalent to. I believe if we go back to the 160 degree -- a little bit before my time, but I believe the 160 degrees is based, I'm told, on the -- reduction for salmonella. If that 152 degree, that scenario we just went through, equals that, then we have an equivalent standard, and it's just as equivalent and enforceable as the regulation.

MR. DEVINE: Well, your answer to my question is yes, and there will not be any consistent minimum floor for what the USDA still represents. Is that what I'm hearing? It can be 150 degrees at one plant, 165 at another, 132 at another? Just in terms of --

MR. SMITH: As long as it's equivalent to what exists today, and so it would have to show equivalency, and so it has to be able to result in that -- reduction in salmonella which we -- and that's what we'll be training our inspectors. We're not just opening -- opening the door here to anything.

You have to have a scientific basis that shows that you have a kill step and what that kill step means, and we are going to be looking for equivalency to what we have now.

MR. TAYLOR: Tom, let me -- this issue of how we shift from command and control regulations prescribing detail with legally binding force and effect how a company cooks a products, the shift from that to performance standards and HACCP is very much at the heart of what Pat Stolfa is going to talk about because one of our regulatory reform proposals is to modify the existing command and control regulation for cooked products to incorporate a performance standard option which, again, we'll talk about and which provides -- the point is it provides a legally enforceable basis for ensuring that the same standard of safety is met.

And when we say we need to review existing regs to make them consistent with HACCP, I mean, one reason we have to do that is because we can't have exist -- co-existing one regulation that purports to say there is only one way to produce a safe cooked product to a certain performance standard while we've got HACCP saying that it's the plants responsibility to design a system that meets an appropriate performance standard.

I suppose if there -- you know, if we identify requirements and conclude that there is in truth and in fact only one way to produce a safe product, then that perhaps is a reg that remains consistent with HACCP, but this is the whole transition we're talking about, and so I think we ought to try to -- on that particular issue, let's -- let Pat walk through in substance when we get to that how we're proposing to do that for cooked products.

MS. HANIGAN: Mr. Taylor, can I make one point because I think we're getting confused. This is Katie Hanigan with Farmland. I think it's important also when we're trying to help the inspectors with validation that they understand if they come out to validate our program and they see that a critical limit was exceeded and we took corrective action as per our plan, that our HACCP program is working.

We don't want to get tangled up now where if we exceed a critical limit and took corrective action, that it means the program is not correct. I mean, we need to get that clarified, too.

MR. SMITH: Absolutely. Absolutely, and I believe I said that both yesterday and today. That if the plant is taking -- because that's one of the basic seven principles. They have identified corrective action, and the plant takes that action, the system -- that is -- that is verification that the system is working.

MS. HANIGAN: Right. Thank you.

MR. BILLY: All right. I think we're going to move on. Ralph?

MR. STAFKO: Okay. Thank you, Tom. I'd like to spend a few minutes going over generally the issue of regulation reform and what it is in today's context. Most of this is going to be in the advance notice proposed rule making which is one of the six documents which are listed in this backgrounder which I believe everybody has had a chance to look at.

I'd like to tie that in in a few words with what the layering issue is as I perceive it and then spend some time going over in a little more detail these documents which are in the backgrounder.

Mike Donovan raised the point earlier which I think is germane about the confusion that I think a lot of people have connecting our food safety initiatives and HACCP with our reg reform initiatives. The latter really encompass more than just food safety and HACCP. Certainly, that is a prime motivation for why we're doing regulation reform to the extent we are today, but regulation reform does include more.

Earlier this year, shortly after we issued our proposal, President Clinton directed that we as well as the rest of the executive branch agencies undertake among other things a page by page review of all our regulations. Fortuitously, one of the things that we were review them for was to see if there were ways that those regulations that we needed to keep could be made more performance standard oriented and less

prescriptive, and this was very much in line with where we were coming out in our HACCP deliberations as far as things that needed to be done with our current regulations.

The page-by-page review that we conducted -- this was for the national performance review as the executive agency under the President or actually the Vice President that was overseeing this activity -- was looking for us to eliminate all the unneeded regulations, to indicate what other remaining regulations should be revised, and also to make those remaining regulations easier to use, focusing as is also a reinvention of government goal on serving the customers.

So while we were in the process of making this review, we at the same time tried to identify all those regulations that would be affected by our HACCP proposal, those regulations which we felt would have to be changed in some way to accommodate the HACCP system as we had planned it or proposed it.

As a result of our page-by-page review, we identified I think about six percent of our actual existing regulations to be eliminated, about -- close to 70 percent revised in some fashion for the reasons I mentioned.

In doing that review, we also took a cold look at our regulations in their entirety and came to the conclusion basically that we had to redo the whole schmere. They are not very user friendly we had to admit, and there's a lot of reasons for this, and a lot of it is inherent in how we

regulate and how things have evolved over the years.

I think it's useful to recap basic rule making procedures. There's basically two ways in which we, like other agencies, can establish rules. One is through case-by-case adjudicatory kinds of activities. The other is through notes and comment rule making.

Meat and poultry inspection is inherently a -- an adjudicatory kind of an activity. Inspectors and inspection program people make thousands of decisions every day, and in the totality and precedence that evolve from those decisions, you develop rules. It's management's job, of course, to ensure that the people who are exercising this discretionary authority have the training that they need, the administrative support they need, and the various kinds of direction that is required.

Over the years, we've developed a body of documents that has been talked about already as a source of some concern. Things like our manual, MPI manual, directives, MPI bulletins, a whole variety of issuances that are sent out from Washington and from the regions and other folks at various levels of management to people out on the front line in an attempt to provide them the information that they need or that management feels they need to be able to do their job well.

These are also provided automatically to all the inspected establishments. They provide a valuable source of guidance at a minimum to them about what the inspectors are doing. Many of these materials have been drafted in such a way that many times

they can be viewed as functional regulations. We take a mae culpa for that. That's happened in the past.

On occasion, I understand that inspectors rely on these and treat them as if they were rules. Legally, we can say this is not the case. They are guidelines. Inspectors are exercising their discretion, but the way they choose to use those is something that we have to cope with and, hopefully, something that can be fixed as we revise our regulations and clarify what it is that inspectors do and what it is that the industry is tasked with doing in the regulation.

The APA rulemaking activity has been, of course, a more recent development, and we have over the years promulgated a variety of regulations, and in the context of our inspection activity, issues come up that require some kind of across the board solution, and in those cases, we have in many times put together regulations to address those problems.

Unfortunately, looking at it retrospectively, it has been kind of a hit or miss activity. Our regulations are not consistent. They're not very well organized. As I said, it's often not clear who is responsible for what, whether it's the inspector or whether it's the plant who is charged with doing a particular mandatory item in a plant.

There's also a lot of redundancy. This is especially true in the case of the meat and poultry inspection regulations. The poultry regulations were adopted at the time that the poultry inspection came under the same management as meat. It was

always kept separate and still is today. So consequently, there's we figure well over a hundred pages of virtual duplication in our regulations.

Perhaps just as much of concern is the fact that a lot of the regulations that perhaps should be identical in those two provisions -- or those two areas of regulations are not. We did a side by side review a few years ago of the meat and poultry regs that highlighted a number of areas where there were differences that one could have a difficult time justifying and that have in some cases been asserted as being unfair to one segment of the industry or the other.

These are all things which we propose to address in our comprehensive regulation review which we are in the process of undertaking as we speak. The ANPR is going to have attached as an appendix the -- both the initial list that we provided the Vice President earlier this year and a separate list of those regulations, a subset of the original list, and we've amplified it, which attempts to identify all those regulations that we feel are going to have to change to accommodate HACCP, and we can -- I'll list those shortly, at least some examples from there.

Layering. We on the staff last year when we were getting into HACCP and getting enthusiastic about all the new things we were going to be doing made a conscious decision that the changes to the existing regulations were something that we could address after we had fine tuned what it was we were going

to be doing in our new regime, what this new paradine was going to look like, and the idea was that once we had that defined, we could go back and better define what it was that needed to be changed.

And that's also another reason why we had the fairly lengthy phase-in period. We knew that it was going to take time to go back and change those new regulations -- those old regulations to accommodate the transition to our new system, and it seemed fairly obvious to us as it turned out, of course, to many of you folks it wasn't very obvious, and I guess it wasn't very obvious to the House Appropriations Committee folks either.

And so we had to take a bit of a mae culpa on that, too. We didn't do a good job of communicating our intention to address our current system, and we should have done a better job.

However, having refocused our activities, our attention, we in addition to holding these meetings are -- have increased our efforts at starting our reg reviews, and we have put together this package of six documents, Federal Register publications which is going to be our first installment on our comprehensive regulation review.

If you'll turn to your backgrounder, the advance notice of proposed rule making, there's basically that. There are four proposed rules, and then there is a final rule in the labeling area. The ANPR, as I said, outlines our overall long-term reg reform agenda. It also includes a piece on standards of identity.

Standards of identity have been questioned in terms of their validity and merit. They are very prescriptive and in some ways prospective, and many have said our antithetical to the concept of performance standards. However, we know there is also a lot of reliance on them amongst many in industry, and we at this time didn't have a particular handle on how to propose changing them, much less doing away with them, but we are open to people's comments on what we might do differently in the area of food standards and composition, food standards by identity and composition.

Performance standards, I'll defer to Pat Stolfa on that, but these are proposed rules which we hope will provide a demonstration of how we intend to use performance standards in our new HACCP approach to regulation.

The third document is a proposal to eliminate a number of prior approval requirements. As Mike said earlier, we are proposing to do away with the prior approval requirement for facilities, floor plans, for specifications of equipment, and for most of the partial quality control plans that we require prior approval of.

The next proposed rule is on substance approval. This is a proposal which would basically do away with the current requirement in our regulations that substances to be added to meat and poultry products must be approved by us and be listed in our regulations before they may be used. This requirement is on top of an existing FDA requirement under the food

additive provisions of the food, drug, cosmetic act that they approve all those same substances for their safety.

So it is in a sense a duplication of effort, and we are proposing here to basically piggy-back on FDA's rule making so that there's only one federal rule making required for substances that can be used in meat and poultry products.

Let's see. The next document is a proposal to allow -- and John McCutcheon can speak to this in more detail -- but this would allow the use of a modifying nutrient content claim in conjunction with the name of a standardized product. Even though that product doesn't meet strictly the requirements for that food standard, you can still use the standardized name as long as it is -- the product has been changed only to comport with the requirements for the nutrient content claim.

Finally, we have a final rule which is a follow up of a proposal issued earlier that would take many of the current label -- prior label approval requirements and turn them into generically approved labels, that is, labels that don't need to be approved prior to their use.

The prior approval process itself is something that continues to be looked at and will be open to further comments and suggestions on that particular process in the future.

That is basically the documents that we hope to publish, like I said, in the very near future. They're all in final clearance right now. We have enough feedback from folks in the administration that are reviewing it that the essence of these

are -- are within the scope of their approval, but some of the details, as we said to them were details, are still being looked at, but we do hope they'll be published very shortly.

The list in the ANPR of documents that -- or existing regulations that we hope to address prior to the implementation of HACCP is a very tentative list, and I think, again, Mike said we're hoping we can get a lot of input on this issue from everybody, both in terms of the scope of the list and in particulars, insofar as how things should be changed.

Some of the areas are basic, like definitions. There are conflicting ways things are defined in the meat and poultry regs, for example. The application for inspection. If we're doing away with the requirement for facility plans, that needs to be changed. Inauguration withdrawal of inspection, the need to clarify the role of what inspectors do is implicit in that area. The question of appeal has been raised and the relation between the general proposition that you just appeal up the chain of command as opposed to a more formal appeal procedure such as we have elsewhere in the regulation for withdrawal of inspection. Those things have to be worked out.

The area of facilities for inspection, things required for sanitation. Again, the hope and the goal is that we can make sure the regulations include only those things that are absolutely required and rely primarily on the industry to decide exactly how it is they achieve those requirements.

A lot of things in the area of reinspection have to be

addressed. There is some concern about access to information and record keeping. Those would have to be addressed as well.

This list is not addressing slaughter activities. We decided that that is an issue we intend to address a little bit later in keeping with our still planned for phase in of the HACCP requirements. We are addressing those things that we feel we're going to have to fix first and are allowing ourselves a little bit more time to do everything else.

That's all I have to say for now.

MR. BILLY: Ralph, you mentioned a couple of percentages. Would you repeat those in terms of elimination and then modifications for HACCP?

MR. STAFKO: That -- that wasn't specifically for HACCP.

MR. BILLY: Okay.

MR. STAFKO: That was in response to the national performance review requirement for an estimation of how many of our current regs we could eliminate, and it was I think a little over six percent, and how many of the remaining would be revised or reinvented in some fashion, and it was up close to 70 percent.

MR. BILLY: Okay. Thanks. Pat, do you want to talk specifically now about the performance standards and --

MS. STOLFA: Sure.

MR. BILLY: -- the examples?

MS. STOLFA: Pat Stolfa, FSIS. As Ralph mentioned, among the six documents which will appear in the Federal Register as

part of our regulatory reform initiative will be a proposal which takes three of our existing regulations and supplements each of those three existing command and control regulations with a performance standard.

And this has been an interesting and I think educational experience for us to make sure that -- that we could do this. I'm only sorry that it's not available to you so that you could see it and get perhaps a better understanding of what our vision of performance standard regulation is.

The three regulations -- I will do my best to sort of explain this conceptually, but I -- in a lot of ways, you need to read the proposal to get the flavor of it. The three regulations we chose to make this transformation and add the transformation to our existing regulations were the regulations governing cooked beef, the regulations governing cooked and partially cooked uncured patties, and the regulations governing cooked and some partially cooked poultry.

And they made a nice package because they had a similar set of performance elements, and one way I think to perhaps understand the move from command and control to performance standards is that when we move to performance standards, what it seems to me that we're doing is that we're exposing in a more transparent way the scientific and technical underpinnings of our command and control regulations.

And what we're proposing to do is to regulate on the basis of the scientific and technical underpinnings, but we continue to

keep in the regulations the current command and control and prescriptive approach so that any company that wishes to remain with the current approach and does not care to change its process has a way that it can comply with the performance standards. There's a sure way to comply with the performance standard is if you do the things that are in the existing regulations.

So what -- we're sort of going backwards in certain respects. We kind of have a specific approach embodied in our existing regulations, and what the addition of the performance standard regulation is that it provides a more general approach which we believe offers flexibility over the -- over the long term in particular for companies that wish to innovate.

Now, let me talk more specifically about what are the elements of the performance standard for these three regulations. For each of these three regulations, there is a lethality standard. That is, a kill step that needs to be met. It might be expressed in terms of 70 salmonella kill, 5-B salmonella kill, but there is a lethality standard which is a key element of each one of the performance standards proposed for these three sets of regulations.

The second element is a stabilization standard. You need to make sure that after you accomplish the kill, you don't -- you -- you rapidly cool the product is the way that it's most usually accomplished under -- under present regulations, but the standard is that you need to make sure that spore-forming

bacteria are not able to grow or are not able to grow in amounts that present food safety hazards, and so that is the second element of the performance standard.

And the third element of the performance standard is a handling standard. You need to get the product into its final packaging without introducing any other pathogens, and so these are the three basic elements of the performance standards for each of these three sets of regulations.

Now, what if you're a company that doesn't want to following the safe harbor which the existing regulations provide for you? What do you have to do? What you have to do is, let's say -- and my understanding is that the most frequent thing that people probably presently ask for about the meat regulations is some alternatives to the stabilization standard. That is, they want a different -- a different cooling rate or a different cooling procedure than are prescribed in the existing regulations, and we get requests to look at those alternatives.

We won't have to look at those any more because what you will do is a company that wants to approach this a different way will go to a processing authority and seek from a processing authority a processing schedule that meets the performance standard. If you want to change your approach to handing, in other words, you would seek from the processing authority a processing schedule that gives you an alternative way to ensure that the standard for growth of spore-forming bacteria is met.

In addition, after you got the processing authority to give

you a process schedule, and you make sure that you had corrective actions proposed, and you have a full set of documents, in the plant, we would expect that the company would produce three production runs following this new alternative processing schedule, would hold and would test those samples from those three consecutive runs, and if indeed it was demonstrated through that that the company was able to follow the process, the alternate processing schedule, and to meet the performance standard, then that alternative approach would become the standard way in which the company would accomplish this performance standard.

So that -- this gives companies more flexibility we believe to use alternative but equally effective standards. We did not make any change in the food safety standard when we translated the command and control regulations into performance standard regulations. We wanted to make it very clear that this was simply a translation from one kind of approach to another kind of approach, and that it makes -- it made no difference in the level of food safety that was achieved by those two differing approaches to regulation.

And so that's what's in the proposal on performance standards.

MR. BILLY: Okay. With that, I'd like to open it up again for discussion. Lou Gast, you deferred. Is he here? Okay. Marsha? Okay. Marty.

MR. HOLMES: I'm Marty Holmes with Southwest Meat

Association and on behalf of SMA, I'm here as well as -- we represent a large number of small and medium sized packers and processors in the southwest.

Yesterday, I want to obviously want to commend you on what I've seen so far, but I do want to go on the record as in favor of a total plate count versus a pathogen specific micro as a baseline trend analysis. Certainly, as what I've seen right here that we -- Ralph and Pat have both just gone through -- commend you on the -- getting rid of the unnecessary and redundant regulations that you're proposing here.

We do have a mass educational effort on both of our parts as industry and inspection to get our folks up to speed as to what HACCP is. The one thing that we are seeing is HACCP is not only the right thing to do because it's coming from the reg side. It's the right thing to do for our customers, and we see that our customers are coming to us saying, hey, do you have a HACCP plan in place?

And they're wanting to come in to our plants and see what we're doing, and so it's -- for us to stay in business, it's -- we've got to have customers. Obviously, we have to meet regulations, but if we don't meet our customers' needs and their expectations, then we're not going to be in business either.

So we see as much HACCP being forced on us, happily so by our customer base as opposed to just on the regulation base.

In terms of layering of HACCP, I see that the only way that

HACCP layers, it layers so that it encompasses GNPs and SOPs. Other than that, you know, we certainly feel that there will be organoleptic inspection, still expect inspectors to be in our plants, probably more on verification and processing plants, more the verification role, but certainly be there to see the product through. As it relates to slaughter plants, we see that more as a continual process of inspectors in our plants.

The appeal process when something does get out of control, I certainly agree that if it is in control if corrective action is taken, but when an appeal does happen, it is going to have to be corrected very fast -- very quickly. When you have a product on the line and customers on the line, they're expecting shipments.

We have trouble now even in regional offices getting questions answered because of the staffing problems, and I understand where you all are on that, but that's certainly something that's going to be even a greater problem as this is implemented.

We feel that joint training of FSIS employees and inspectors in HACCP along with industry, it's preferable that we're all being trained on the same page from the same document and certainly feel that what the international meat and poultry HACCP alliance has done something that you all should take a look at very closely to use in training your inspectors.

Other than that, you know, I've heard a lot of people say that the devil is in the details, but from the industry

standpoint, I think it's the devil in the details that -- that from the industry standpoint scares the hell out of us. You know, we've talked about a lot of things in the last two days, but there hasn't been a whole lot of detail, and that's -- that's what concerns us at this point. Thank you.

MR. BILLY: Jim.

MR. HODGES: Jim Hodges, American Meat Institute. I have about two points of clarification. All this is related to reg review and then some questions.

I'd like to clarify the time table to start with. You're going to put out an advance notice of proposed rule making in the near -- in the next few weeks prior -- correct? After that -- soon. Okay?

MR. TAYLOR: Yes.

MR. HODGES: And then we are talking about putting out a final HACCP pathogen reduction rule early next year which would mandate the near terms to be put in place in the spring to summer, but I believe -- and that your commitment is to complete the regulatory review prior to HACCP implementation which means between now and sometime before the HACCP portion of the mega reg goes in place, that you will have put out not just the ANPR but also put out a proposal and also put out a final rule. Is that correct?

MR. TAYLOR: Any -- any regulations that need to be changed to be consistent with HACCP in the way in which we've been discussing that will be completed before plants are required to

implement HACCP.

MR. BILLY: The answer is yes.

MR. TAYLOR: Yes, we have a lot of work to do.

MR. HOLMES: But the near term mandates will go in place prior to the completion of the regulatory review.

MR. TAYLOR: I mean, the whole issue of the timing and manner of the near term, you know, measures is -- well, we've got several days of meetings left and decision making, so I mean, there's certainly -- there are issues about timing of implementation of the -- and as well as manner, so we can't say today what the time table is for the near term.

MR. HODGES: That leads me to a comment. Then I'll come back to another clarification.

MR. BILLY: Before you move on in that, though, I'd like to make a suggestion, and I'm not sure I said this before. We did have on the first day at the bottom -- the end of the first day the issue of timing, agency implementation, industry adoption. My suggestion is that we add that on to the agenda for the 29th, and that after the discussion on the specifics in terms of the near term as well as these discussions, we come back and have a full discussion on timing and implementation, and it probably makes more sense now in hindsight to have had that at the tail end.

So that's my proposal to come back to that. Keep going on your questions.

MR. HODGES: On the timing, you want to defer that until

Friday. Is that what I --

MR. BILLY: Well, keep going in terms of the specific questions, but regardless of what we talk about right now, I want to come back and have a full discussion on timing on the last day.

MR. HODGES: Well, it just -- if you look at the schedule as I outlined it, I think you generally agree that that was the case. It certainly seems to me --

MR. BILLY: Specifically agree.

MR. HODGES: It certainly seems to me like --

MR. BILLY: -- specifics.

MR. HODGES: -- that we need to rethink our work ordering, what we're doing here because in terms of the regulatory review, how can you finalize a -- the HACCP rule, HACCP pathogen reduction rule without having a definition of what the regs will -- supposed to look like under that rule and furthermore, that you have the definitions which in turn dictates the inspector's function in a plant.

It seems like that you need to have the foundation built here before you make the final determination on what that -- what that HACCP and pathogen reduction rule ought to look like. At least, logically, it seems that way to me, and then I'd like -- like to follow up with just a couple other clarifications.

MR. TAYLOR: Yes. I think from our standpoint, the logical order is as we've laid out, and the reason is that the regulatory reform, the changes in inspectional practice are

being built around the HACCP concepts and not the other way around. I mean, HACCP is the framework that we are creating for the future of the program, and we're going to do whatever regulatory reform and modification of inspections appropriate built around that framework.

So that's our logical -- that's our rationale for the order of things.

MR. HODGES: We've also got some conflicts that exist. You published this week the preliminary reports and the top to bottom review. In that, you ask for comments on a variety -- well, you ask for comments on the entire report, but some of the things that's listed in there is prior approval. How you plan to handle prior approval.

Should we be commenting on the top to bottom report or should we be commenting on the future -- the soon to be published proposed rule that will eliminate prior approval?

MR. TAYLOR: We are very -- as you can tell, exquisitely open to comment.

MR. HODGES: Will they differ?

MR. TAYLOR: But that's a very good -- all kidding aside, a good question, Jim. The rule making proposals are -- to the extent an issue is being addressed in the rule making proposal, I mean, that obviously becomes the operative document, and so we, you know, you can look to the top to bottom for ideas that might influence your reaction to the proposal, but when we proposed elimination of a prior approval system, that is our

proposal, and we invite comment on it.

Let me just say, I mean, the whole issue of commenting on the top to bottom review, I realize it's going to be challenging if you attempt to be comprehensive, and indeed as we say in the Federal Register document, when you read the reports themselves, there are all kinds of internal, sort of competing recommendations with, you know, among team reports. I mean, this was -- this is not held out as a cohesive set of agency positions. This is a lot of raw material, ideas, analysis, options generated by employees during a certain period of time this summer when they were asked to do this.

So I mean, admittedly we now dump it out welcoming comment on whatever aspects obviously interest you to comment on, but it's between the top to bottom documents and the regulatory proposals, obviously, those are, you know, in some cases our thinking institutionally has evolved such as on prior approval beyond where the teams that looked at that issue in top to bottom was. So you got to -- those take precedence.

MR. HODGES: One final comment is you've done a substantial amount of work on this regulatory review already, obviously, because you've at least categorized the regs by the need to revise 70 percent and 60 percent are going to be -- or six percent is going to be eliminated and so forth.

You've also submitted information to the Vice President's regulatory reform. It seems -- it would seem to me that that kind of information that you've already preliminarily done

would be very useful to this group in terms of providing some framework, specifics, and so forth for a more informed kind of discussion about this whole issue of regulatory review.

We could put some meat on the bones without talking in some of the generalities. One, is that possible, and secondly, I assume that since we've all characterized the near term mandates as command and control, that those also be included in the regulatory review for elimination.

MR. TAYLOR: Well, on the latter point they are. I mean that's the whole -- not, not elimination. In some cases elimination, yes, that's command and control, I mean shifting to performance standards on those.

I mean on the issue of some opportunity for further -- for dialogue like this based on the identification of candidates for review or repeal, I mean, I'm personally extremely receptive to that. I think if in fact, you know, if we could get this group together again in October or whenever would be appropriate to focus in particular on that ANPR and the way we laid those issues out and the -- the things we identified. I mean I think that from our standpoint would be just very valuable.

MR. HODGES: Thank you.

MR. TAYLOR: And I think in fact -- I mean, given the fact that we have got a lot of work to do in a very compact time period. I mean, that would make it the more important I think to have a chance post ANPR but, you know, before the next rule

making steps to sit down.

MR. BILLY: Joe?

MR. POCIUS: Thank you. Hello? Okay. Thank you, Mr. Billy. I want to bring up a point that I originally brought up very early in the spring at one of the public hearings, and you graciously suggested that we should put it in our comments, and we did, and I want to bring it up one more time.

When we're talking about performance standards, we go through -- through a process authority or otherwise. We develop our CCPs. We establish our critical limits based on food safety. However, product quality market demands -- let's take for instance the food safety temperature would be 160 minimum instantaneous internal, but the product quality demands 175 degrees for a roasted look or -- or whatever. Okay.

The proposal states that inspectors will enforce at the higher temperature even though that's not a food safety issue. I want to make certain, and it's really not a question, I'm -- I'm suggesting that if it has not been changed that we do change this, that the HACCP program enforcement is at the food safety critical control limit, period.

And as long as we're -- we're talking about this issue now I can -- I've really -- I've waited all day to -- to get into some of the details on this and -- and I'd like to suggest that if that has not been done, that we do consider that because otherwise you're going to be failing perfectly safe products if -- if we're -- if a HACCP critical control limit is enforced at

175. You fail it. You have problems in revalidation. You got a tag product, control product. All the while that product is perfectly safe for consumption.

The second thing -- I'm assuming that we were -- we're talking about cooked product and, of course, that's the easy way out of things -- I'm assuming that the lethalities we're talking about are going to stay at current levels. So if it's currently a 5-D kill as for roast beef, then anything else you develop for roast beef or turkey or whatever is based on a current lethality.

Now, how are we going to do this in raw product, and how should we interpret a performance standard for raw product?

MS. STOLFA: I think that's what we're going to talk about tomorrow -- that's what -- that strikes me as the conversation tomorrow and that what we were talking about in the way of --

MR. POCIUS: Couldn't bait you into that one, huh?

MS. STOLFA: Not today.

MR. BILLY: I think we do need a discussion about the 175 example that you -- you mentioned. Yeah. Bill?

MR. SMITH: Yes. Exactly what you said that -- that we're going to be making our food safety decisions on the food safety, the critical limit, and what we are hoping is that the HACCP plan that will identify the food safety limit as the critical limit and not the quality standard. The quality standard becomes a control point.

So -- so we're hoping that's differentiated, and then if it's

not differentiated -- well, then -- absolutely. We need to have the critical limit that you're going to use for that product so -- so you need to make that decision I think when -- when you're setting up your HACCP plan -- that if you don't differentiate, then we are going to have to enforce what's given to us which is the higher limit because there's no differentiation made.

What we would expect is we would see -- I don't know, 160 for the -- for the critical limit and 175 if you want to use for a -- a control point that that's what -- but it would be differentiated and -- and hopefully, the critical limit in the HACCP plan will identify the temperature you want to use for the food safety.

MR. BILLY: Okay.

MR. TAYLOR: And that's what we would enforce?

MR. SMITH: Yes.

MR. BILLY: Dane?

MR. BERNARD: Thank you, Tom. Dane Bernard, National Food Processors Association. We had this discussion a few months ago, not that it was in a formal context, but that is -- is going to be a very tough situation. I can guarantee you the first day that you go out there, you're going to find people who put their critical limit as their operating parameters.

We find this all the time, and if you go tagging up company A's product, which is just as safe as company B's, and company B is in business in shipping, I would think that that would be

a -- a legal situation you wouldn't want to get into.

Now, you've got office of general counsel here. Maybe you ought to ask them what their opinion is. You know, you're going to have people putting things into these plans because the knowledge of what a good HACCP plan is not yet universal, and I think we're quite a bit of ways away from that. You're going to find these situations all over the place and I think that -- that the regulatory limit should be the safety limit, and that should be your enforcement limit.

If somebody is not educated enough in what goes into a HACCP plan, and they put 175 because that's what they cook to because they like the quality at that, and they put it in there and they cook one day at 174, the product is safe. You've got to look at it in that aspect, and that's going to happen over and over, and I think it's a very difficult situation. People are going to have to understand that. Thank you.

MR. TAYLOR: Dane -- Dane, let me just respond to that. I mean, I can -- I can picture the situation that you've described actually happening, and we would have to deal with that in sort of some practical way if we confront a plant, you know, operator who has in fact developed a HACCP plan that incorporates not real safety critical limits but some kind of quality limit and -- and presumably, that could get sorted out on the -- you know, in some practical quick way.

But be clear that HACCP is about the plant taking responsibility for designing a safety system, and there is a

training burden on industry just as is a training burden on our inspectors and part of it will be. And trade associations like yours will no doubt play a role in ensuring that -- that people are training to write HACCP plans that embody critical limits in the safety sense of the term.

But I mean, I think this is not an insurmountable problem on either side but the -- but HACCP is going to delineate some responsibilities for plants that they will have to meet to write plans that incorporate safety limits.

MR. BERNARD: I -- I agree, you know, it's not an insurmountable problem, but we see this over and over. It is a problem that you should anticipate and that you should have some resolution for, and I think that the solution of reacting to that situation as if it were a safety hazard is the wrong way to go. Absolutely wrong.

MR. TAYLOR: It's not a -- right.

MR. BERNARD: If the plan is --

MR. TAYLOR: It's not a --

MR. BERNARD: If the plan is flawed because you put the wrong critical limit in there, and I think when we met earlier I used a rather crude term for it -- for describing how that got there, but I won't use that in this on the record meeting --

MR. TAYLOR: Tom -- Tom instructs me that this is an issue that we will address in the preamble to the final ruling. It clearly needs to be -- we need to lay this out and explain how

we would handle it.

MR. BERNARD: It's -- it is going to happen. It's going to happen I don't know the temperature it's going to happen with every critical limit if that means anything in terms of safety. You're going to find operating limits not critical limits in probably the first generation of HACCP plans that you run across out there. So you know, be forewarned.

MR. BILLY: Katie? Is this on this point? Yeah.

MS. HANIGAN: Katie Hanigan with Farmland Foods. Katie Hanigan with Farmland Foods. Question for Pat. Since we're going to look for in the example you gave us -- 70 reduction, I am assuming that we would not be monitoring our first three production lots. Would we not need three inoculated studies? Just for clarification.

MS. STOLFA: The -- we expect the processing authority to -- to do all of the work that should be done outside of plant before the -- as the process schedule is being developed, and when the process schedule is in -- in view of both the processing authority and the client company completed, that's the time to move to the in-plant trials which essentially demonstrate that the alternative approach meets the performance standard.

MS. HANIGAN: So would it need to be an inoculated study in the plant?

MS. STOLFA: I don't think we've specified that in here. I'd -- I'd have to look exactly at what -- at what we say in

that regard.

MS. HANIGAN: Well, if you're talking a seven log reduction in some of the stuff though --

MR. BILLY: Okay.

MR. EMERLING: Stan Emerling. Just as a follow up. Do you have any idea what that lot size is going to be when you sit three runs? I mean --

MS. STOLFA: No, we didn't specify that.

MR. EMERLING: So, it could be 50 pounds?

MS. STOLFA: Pardon?

MR. EMERLING: It could be 50 pounds?

MS. STOLFA: We didn't specify that.

MR. BILLY: I think it would be --

MS. STOLFA: It was a normal production run is -- is I believe how we talked about it.

MR. EMERLING: Okay, well --

MR. BILLY: Mike?

MR. DONOVAN: Yeah, Mike Donovan again. My question comes back to just a clarification here is -- we had somebody ask about a temperature higher than the one before. Let's take ham, for instance. If you're meeting 145, you meet a temperature, but if you're saying baked ham, now you're into a different -- baked ham has to hit a 170 even though that isn't a health issue.

Does the inspector tag that product if it doesn't meet the 170 in baked ham, and the baked ham regulation doesn't get

knocked out on the standards issue?

MR. SMITH: The inspector -- inspectors will still be -- at least for start up, will -- will still be verifying label accuracy. I would see that as a label accuracy check probably not near of the frequency that -- certainly not at the frequency that -- that the HACCP food safety checks would be done but if -- but, you know, if a 170 is what is driving the baking label and they're labeling as baked ham, we would be at some frequency looking at that.

MR. DONOVAN: So they would tie up that product if -- if they had taken the check and in that frequency found that it was not meeting that, is that correct? Well, that's what I think I'm hearing you say, right?

MR. SMITH: I'm saying they would take their action under PBIS now, which is that they would classify a deficiency, and if -- and if that deficiency results in an official control action, they would do that.

MR. DONOVAN: Okay. Another question to follow up on Pat -- on what she was saying about performance standards, and one of the things that you were going to -- one of the items that you were going to do is those prescribed poultry products. And one of those would be, I imagine then, cooked cured poultry such as chicken franks that you have 155 degree. Would we include meat franks with the same prescription when we're doing this reg here because that's probably one thing that falls through the line.

We do not have a temperature -- for like meat franks you could have 50 percent poultry and meat. It depends on which legend you put on the product. Are we going to cover those particular things under this proposed rule?

MS. STOLFA: This proposed regulation deals with cooked beef, cooked roast beef, cooked and partially cooked patties, and some cooked and partially cooked poultry products --

MR. DONOVAN: Okay, I'm talking about the --

MS. STOLFA: -- not all of them.

MR. DONOVAN: No, I'm talking about the last ones though.

MS. STOLFA: Yeah, and I don't believe that those products are covered, and I can give you the exact citations. It's not my understanding that those products are included. As I -- what I explained before is basically we -- we expect that the underlying scientific work is completed by the company and the processing authority prior to the completion of the alternative process schedule.

And then what goes on in the plant is a production -- three production runs following the -- the process schedule which has not been grabbed out of the sky but has been developed by the company and the processing authority, and the three production runs need to be sampled just to make sure that they are meeting the performance standard.

And essentially for fully cooked products, and I -- I really haven't talked about partially cooked patties and partially cooked poultry because that's a little more complicated, but --

but for the fully cooked products, what we are expecting is no pathogens in the finished product, and so that's what the in-plant sampling would -- would be designed to demonstrate.

That when we follow this schedule that the processing authority and we have developed together, when we follow it, it works.

MR. EMERLING: Pat, all I want to know is the definition of processing authority. Does it -- does it mean any reputable or --

MS. STOLFA: We are not proposing a specific definition of processing authority in this regulation.

MR. EMERLING: But you can't tell us what it is now?

MS. STOLFA: It's -- it has several features. It's -- it's basically that it's -- it's a -- a company that has the necessary qualifications in terms of their ability to -- to perform the -- the underlying scientific work which would support an alternative approach, and so it's kind of a performance type of -- of definition of processing authority.

We -- we don't prefer to get into the business of listing, approving or disapproving processing authorities, so what we tried to do was to capture the qualifications that -- that we would expect. They need to have access to facilities -- laboratory facilities or other facilities that would be necessary to carry out the work which would lead to a process schedule which would be acceptable.

MR. BILLY: --

MS. STOLFA: Oh, I'm sorry. I didn't mean to say just companies. I mean it could be academic institutions. Generally, I view these as people who are in it as a business, so it's a business -- it's -- it's not a -- I don't mean to imply that it's some other meat processing company. It's -- it's more likely to -- to be -- oh, maybe a consulting group, but no, it's a business so I presume that it would have that status.

MR. BILLY: I saw another name plate. Jim was it?

MR. MARSDEN: Yes. I have some just general comments on the coordination of the regulatory reform initiatives with the implementation of HACCP.

MR. BILLY: Jim, Joe's not finished so --

MR. MARSDEN: Oh, sure I'll --

MR. BILLY: -- if there are more general --

MR. POCIUS: Let me just finish up quickly. While we're still talking on the performance standards. Pat, I think we all have an idea of what you meant by the three pieces of a standard lethality. We just talked about stabilization and handling.

Would I make an assumption on stabilization, that would be the cooling -- similar to the cooling directive, and how were you going to put -- how is that -- are you looking for equivalent? I mean, I'm not quite sure how you do equivalency here, and on top of that, the handling, if you'd give us an example of what you -- what you have in mind for handling?

MS. STOLFA: The stabilization standard expressed as a performance standard is basically there can be no multiplication of toxigenic microorganisms such as clostridium, botchilinum, and no more than a one decimal log multiplication of clostridium profringens within the product. That's the performance standard.

Now, that's what underlies detailed time/temperature requirements that are in -- in our directives in -- in certain instances. There's a cooling directive --

MR. POCIUS: Right.

MS. STOLFA: -- that embodies that particular general standard.

MR. POCIUS: Okay.

MS. STOLFA: This is the standard.

MR. POCIUS: All right. So I guess that's what I was getting at. There will be something for process authority to bench mark when they go after this.

MS. STOLFA: Yes.

MR. POCIUS: Okay.

MS. STOLFA: Yes.

MR. POCIUS: Thank you.

MR. MARSDEN: Okay, Jim Marsden with Kansas State University. In terms of coordination of this regulatory reform initiative and the implementation of HACCP and also relating back to several of the things that have been discussed throughout the day, going back to the HACCP round table and

some previous meetings that we had on HACCP, we laid forward what I thought was some -- some pretty good ground rules in -- in terms of the way that the HACCP plan should be developed, validated, and so on, and -- and I recall three principles that I -- I think we got consensus on.

The first was that the HACCP plan should be properly developed and complete, should address all seven HACCP principles, and I think everybody's clear on that. Also secondly, validated to assure that the critical limits in the process adequately control food safety hazards. There's been some probably misuse of the term validation throughout the day but it -- it specifically addresses the -- the effectiveness of the HACCP plan in controlling hazards.

And third, and this is an important one, the HACCP plan should reflect the capability of the process in the individual establishment where it would be applied. And there was a lot of discussion about the need that the HACCP plan be plant, product, and process specific.

Now, another thing that came up but was not resolved was the issue of prior approval for the HACCP plan, and a lot of the things that we're discussing right now relate back to that because if the HACCP plan is not approved or does not receive some previous approval either from FSIS or from a process authority, then that plant is always in jeopardy.

There's no comfort level because a local inspector can make arbitrary decisions about the inadequacy of that HACCP plan and

effectively shut the plant down. And there needs to be at -- at a minimum, a dispute resolution process -- Dane referred to that earlier this morning -- that's very well defined and -- and allows the plant to -- to act quickly to address those types of issues.

But even better than that in my view, and I -- and I think there was a lot of support for this concept at -- at previous HACCP meetings and HACCP round table, was the idea of having the principle plant manager, the -- the inspector, the process authority, all sign off on that HACCP plan so there's some prior agreement that that HACCP plan is -- is appropriate, and that takes away virtually all the discussion that we've had over the last hour or so about mistakes and defining critical limits, and so on.

Without that, I fear that we're going to have a lot of confusion during the first months or years as we go forward with the implementation of HACCP.

The same issues also apply to some of the things that are in the regulatory reform initiative, especially the -- regarding blueprints, equipment approvals, specifications, and so on. If the agency just abandons those functions, and there is nothing else to take it's place, the level of comfort that a plan operates in disappears.

Alan Oser mentioned earlier this morning that, you know, you make a $10 million investment in a plant, and you'd like to have some pretty good assurance that what you're doing is

right, that someone doesn't come in at some other point, you know, a year down the road, and say they don't like the slope of the floor, or they want a drain put someplace else or something along those lines.

The inspectors are there in that plant every day. They have the authority to take action on that plant based on those things. They can say that a piece of equipment is not acceptable, or that the plant facility is not acceptable, and so on, without any kind of a prior approval from the agency or from some third party certification body of some kind.

I don't see how a plant can operate with any level of comfort that what they're doing is going to be acceptable to the local inspector, and I firmly believe that these types of issues need to be fully addressed in the final regulation. Otherwise I think we're heading for some real problems as we go forward with the implementation.

MR. BILLY: I have a suggestion at this point. Why don't we take a 15 minute break, but when we come back why don't we have a -- a discussion about this very question of prior approval and get input in terms of how people feel about that. Okay. About 15 minutes.

(Whereupon a break was taken from 4:00 p.m. until 4:28 p.m.)

MR. BILLY: I would like to get started again. We were talking about a point brought up by Jim with regard to the need for prior approval of HACCP plans or programs in plants and felt that it was worthwhile to have some reaction to that idea,

so I'd like to open it up for that. Rosemary?

MS. MUCKLOW: When Ralph went through this backgrounder, he talked about what we've all heard stories about which was that you were going to eliminate the prior approval requirements for establishment drawings and specs, and equipment and certain PQC programs, et cetera.

The narrative in the backgrounder which I've underlined says halfway down that paragraph, that you're going to do that, and then it says FSIS would continue to hold meat and poultry plants accountable for meeting regulatory requirements.

I'm not sure if that means that you're going to codify everything that we know in the handbook 670 or the small meat plant handbook or triple the size or whatever of those handbooks so that everybody would know what every joint is going to look like on the plumbing system or the roof or the drains or whatever it may be.

I think it would be an impossible task for the agency to try to define every possible -- every possible thing now or for the future on both plants, especially with the changes that we're instituting. You know, I know plants that don't have space on the line to put in a wash system in a kill plant because nobody thought of those systems, the new technology and so on. If they're building a plant today, they build an extra mile on it so they can do that, but the older plants don't have it.

I mean, it's unfathomable. You just can't even begin to plan for the future. And so I've thought about this some, and it

would seem to me that one of the things that you might want to consider as you look at this prior approval issue, and you think about it for an ANPR, is to provide a cost recovery system within USDA within FSIS, that you would on request, and probably more efficiently in terms of time turnaround now and so on, provide a vehicle both for equipment and for blueprints, that companies could submit those requests whether it's their new dicing machine or their -- that somebody's made or whether it's a new facility, and based upon a -- a cost recovery system, that staff could be funded to review and approve it.

Not everybody would need to use that. Those who have engineers on their staff or very qualified people or equipment people who believe that their equipment meet standards next to God might figure that they don't need to use that system, but for many firms that would like the confidence structure, they could get a seal of approval that that piece of equipment or their blueprints on such a date met the requirements.

What really screws us up in the blueprint approval is that somebody needs to submit pasters when they build a vestibule on a door or when they move a patty machine from the west side of room A to the east side of room A or do crazy things like that. We -- we have a lot of nit-picking over blueprints, but fundamental blueprints on design construction to meet certain standards rather than to -- to developing a whole new industry out there, the agency itself may be able to provide this kind of a service on a cost recovery basis, and I would suggest that

you give that some consideration.

MR. BILLY: Now, are there other views on prior approval particularly with regard to Jim's comment regarding the notion of prior approval of HACCP plans? Katie?

MS. HANIGAN: I think Jim's going to make the comment.

MR. BILLY: Okay. Does he have your proxy? Is that what we're --

MR. HODGES: We're just -- we had prior discussion. It's my opinion, and I think some others, that the variability of approval with inspector in charges and what their expectations are even after training, even after extensive training, will be quite variable.

I think that the way I would envision particularly would be to have product category sub-groups formed where, for example, if I want to send my pork, fresh pork slaughter and fresh pork processing HACCP to a group that was trained in analyzing those, my fresh beef to a group that was trained in analyzing those, and then specific processed products. I think you're going to need to form a variety of groups that become your product HACCP experts.

I think the IICs will try. I think they'll be second guessing themselves on how far should they go because they do that today, and they're going to either have to have very extensive training manuals in writing for them to evaluate it or go to the -- or go to specific product area process authorities within the agency that we can send HACCP programs.

The other alternative is to have groups who travel and go around and evaluate the written program as well as the implementation of it. The -- the biggest concern I have is the variability, and I think having a centralized group, product specific, that we can send programs to, to review and get feedback, and that group could start if you have an 18 or a 30 month or whatever it is, that -- those groups can be organized fairly quick so that you can send your programs in. I would guess that it -- somewhere between 50 to 80 percent of -- of the plants have some program written.

We do have customers who come in and review today and so we're reasonably confident. Now, the question is -- that our programs at least meet their expectations, and so there's going to have to be some correlation and discussion. It -- but the other thing is when we do modify them, at least in our HACCP programs, I consider them to be very dynamic because if we change a process or come up with a new process -- or a new method, that changes the process flow.

And so they need to be updated on a continual basis, and if you're not doing that, you're not really letting them evolve. So there will be some conflict there that the HACCP program is changed, and we're going to have to make some accommodation for that. So once approved, if it's updated, it will need to be updated maybe quarterly, to six months, to annually, that it should be then resubmitted, but the resubmission process cannot be a major delay.

It is very frustrating today for me to send in a standard PQC program through five different areas, and I don't know how many different circuits and three different regions, and have them anything from perfect and complimented on thoughtfulness to condemned for being inadequate, and they are identical programs. That's today. So HACCP's going to be a little -- even more challenging.

MR. BILLY: Joe on my left and Joe on my right --

MR. MARSDEN: I guess I have a bit of a question. I'm not clear what the -- what the inspector with the IIC -- what would their role be? I mean as I understand it if I'm taking responsibility, I mean if -- if you're saying, Joe, you have the responsibility now for food safety. I mean we're all clear that I already have that firm belief anyway. But -- but you're saying now, Joe, you have the responsibility now for food safety, and we are requiring you to put together a HACCP program to -- that -- that you're going to take -- that you're going to be responsible for to guarantee the food safety.

I'm not sure what exactly the inspector has to do with whether that plan's okay or not. Or is the inspector still going to be responsible for the food safety to the extent that he's going to view the HACCP program as to whether it does or doesn't guarantee food safety.

Am I going to be responsible for it or is the IIC? I'm not -- I'm not, you know, this whole thing philosophically I am having a real big problem with in general. I don't understand

why the IIC has anything to say about it if -- if -- if the philosophically, some people operate their plants don't feel like they're responsible for the food safety, and so that HACCP plans will then correct that.

So what does the IIC have to do with any of this? And -- and I say that with a qualification that -- that I want prior approval because I know the inspector if he's still there. You know, the same thing, I get a new guy every six months. I even get a relief guy for a week who theoretically you would think, you know, they would just kind of come in and do their -- go through their paces for the week and leave the guy -- their normal IIC alone and that's not the case. I mean this guy comes in with his whole new set of personal problems and absolutely wrecks, you know, geez, I can't believe you guys are operating and -- and, you know, everything's going fine. It's -- its's you can't imagine -- it's -- it's very true.

So what I say is, is what is -- if we're doing this thing as -- as it's being said, what -- what does the IIC have to do with any of this? But then, you know, in the next breath, we say well the IIC is -- you know, has the ability to do all of these other things, so I'm not clear what the role of the IIC is in this whole mess.

MS. MUCKLOW: Tom, can we all say a prayer for Joe with his IICs that --

MR. MARSDEN: I -- I -- rest assured I tell my IIC these same things. I'm -- the IICs I get are very clear how I feel

about everything.

MR. SMITH: Let -- let me address -- the role again that -- that we've laid out these last two days is that the inspector would -- I'm getting nervous about the word but -- validate -- would -- there would be an activity where the inspector would ensure that the seven principles have been carried out.

Food safety is the responsibility of the plant. We -- so we need to be that clear -- clear up front because HACCP is --

MR. MARSDEN: Well, is the inspector going to do that or am I going to do that?

MR. SMITH: You're going to carry out the seven steps as proposed. That establishes the food safety for that plant. Then the inspector's role, and that's any inspector once we have that plan that's valid, and then how you're going to carry out that program. No matter what inspector comes in there, if you're following your plan then -- then all he is doing is verifying that you're doing that. He or she is --

MR. MARSDEN: Even if he doesn't like that plan, that's tough. It's -- it's -- in the plant --

MR. SMITH: If the seven principles have been met, two things are going to happen. If the inspector has a question, then again, as I said earlier, we want them to provide the mechanism for them to get that question answered quickly through science and technology. That's what we'll be training. They're the experts.

Now -- now you have to use common sense here like I said

before. If somebody has 110 degree cooking temperature for frankfurters, I don't think the inspector needs to call science and technology --

MR. MARSDEN: But I would like to think that --

MR. SMITH: On the other hand, on the --

MR. MARSDEN: -- the -- that the owner of the company would not -- the -- that's not --

MR. SMITH: I agree, I agree -- but I mean I have to use broad --

MR. MARSDEN: Okay. That's fine.

MR. SMITH: -- because -- but common sense has to come in here. On the other hand, if the inspector has a question but is not sure, he needs to get -- he or she needs to get on the phone. They need to call the area office. The area office needs to get a hold of science and technology, layout what the concerns are, and get a reading there.

And then which could mean -- it doesn't mean at that moment everything grinds to a halt either. It means that people are now looking and questioning, and they may be getting back to you to ask you questions, but it's going to be in the scientific -- critical limits will be determined. Our expertise for that is in science and technology. Those are the people that I have to answer -- to answer those -- that we're going to rely on for the expertise to make those determinations.

Now, we are going to rely on our inspectors or -- or teams,

that go into the plant just as they do today, to -- if there's a concern to raise that.

MR. MARSDEN: But it would --

MR. SMITH: But the food safety is definitely the responsibility of the plant.

MR. MARSDEN: But it would not maybe be an immediate thing. This would be something that would be up for discussion. This isn't like a today, stop what you're doing thing. I mean this is -- you would envision it would be something that would be, hey, Joe, we have a problem with this one area. You know, we need to -- we need to look at it, and in the meantime I could continue to process because I am economically driven to just in time processing --

MR. SMITH: Okay.

MR. MARSDEN: -- and inventory. I -- you know these -- I do not have the wherewithal or the ability or financial capability to produce product well in advance of my needs.

MR. SMITH: Again, the -- if the seven principles are followed, and I think that's the important part, that we have to get that -- you know --

MR. MARSDEN: Well, how much --

MR. SMITH: -- if they are followed though, we are not going to go in there and stop the operation. If on the other hand, though, in the scenario that we had a critical limit established that is ridiculous and we can all agree it's ridiculous, then the inspector in his food safety role would

take action at that point.

MR. MARSDEN: Well --

MR. SMITH: But again, it's all a degree, but if we don't know, if we have a question, then the action is to find out, to gather the -- again, we're talking about assessment now. We need to get into this -- and I think our inspectors are prepared to do this -- is to get into a system of analysis, look at what we've got, and arrive at a conclusion, and if we don't know, then -- and we need more information, we go get that information, and we'll make that information available to them.

MR. MARSDEN: Well, without trying to continue the discussion, but I understand what you're saying, but -- so if there's a -- if there's a ridiculous critical limit, here you're suggesting that there may be some subjectivity in what a critical limit is or isn't as to whether they do or -- there's some subjectivity as to whether I am or am not following the seven principles.

And you know, it's that whole subjective thing that I have the bigger problem because I see the subjectivity that occurs with my -- with the inspectors that I get in my plant, you know --

MR. SMITH: If the seven principles are being carried out, I mean --

MR. MARSDEN: Okay.

MR. SMITH: -- we could debate this all --

MR. MARSDEN: I agree.

MR. MARSDEN: -- but if you identify a kill step, you need to have evidence that that is a kill step and that that works, and so given that you have all that evidence to indicate that that kill step is effective, then we're not going to go in there and challenge that.

On the other hand, if you can't supply that evidence that that kill step is effective, then we'll have some questions.

MR. MARSDEN: I suppose I still would prefer to have a prior -- prior approval.

MR. TAYLOR: At the risk, Joe, of maybe being a little redundant, I think this issue you've raised is probably the most important single philosophical issue in the whole initiative, in the whole discussion. Who's responsible for what? What is your responsibility as the plant operator? What is the responsibility of the IIC or other members of this agency?

And we have a very clear conception that we're trying to convey here, and Bill said it really. The plant operator is responsible for food safety. He's responsible for the safety of the food that comes out of that plant. The IIC and other members of the inspection team are responsible for holding you accountable for meeting your food safety responsibilities.

Everything we do is not about our taking responsibility for food safety, but we're playing the oversight role to hold you accountable for meeting your responsibility. When it comes to

validation -- again, I think this is a point that came through a little bit earlier -- HACCP, the seven principles of HACCP, make the plant responsible for validating the HACCP plan.

So it's not that the responsibility of the inspector to validate the HACCP plan. It's to verify that you've validated the HACCP plan, and I think the thrust of this is going to be over time, and I understand that the questions you're raising are just so, you know, appropriate and understandable.

I personally believe we're moving towards a regime that is more objective, less subjective than the current regime in terms of the judgments that the inspectors will be making because if you're talking about checking to see whether a plant has validated a critical control point in a HACCP plan, and there are scientific data and studies that -- that are there, that provide a basis for validating that, that's a -- that is a considerably, you know, more solid and objective basis upon which to -- an inspector to make a judgment than the kind of subjectivity that goes into deciding today we're going to worry about, you know, this drip or that drip.

I mean, so again, over time, I think we're moving to more objectivity in the program and not less, but I just wanted to emphasize the point that everything we do is about overseeing what you do in carrying out your food safety responsibility. That's the concept.

MR. MARSDEN: Well, you know, the fact is as I have -- I have reason to have FDA. I have a sandwich operation. I own a

bakery as well. I have a bakery in my plant, and we assemble sandwiches. So you know, I understand that. I understand what it's like to be in FDA. They come around nearly never, and I have -- once again --

MR. TAYLOR: You like that. You like that --

MR. MARSDEN: Oh, I like the USDA guys there every day. They do a good job for me. They help me out. I have -- but the issue is that, you know, in this free market economy, you know, that -- that's what drives me to produce a safe product --

MR. TAYLOR: Right.

MR. MARSDEN: -- because otherwise I have -- I'm not in business. Like I said, it's the whole philosophy. As far as I'm concerned, today I'm responsible for food safety. I will -- you know, if or when HACCP, you know, would become a regulation, I would be required to follow that regulation, and I would be producing paperwork for an inspector.

As far as I'm concerned, everybody already has HACCP in their plants to whatever degree or another they do. I know that I do in mine. I certainly have analyzed, you know, any places where there could be contamination or problems. You know, I've set up things, controls, procedures whereby to avoid having any problems in those areas, and I expect that my employees will strictly follow them.

It's just from that point on, this regulation will then -- you know, will -- will -- it will just cost me money. It will

cost me money in producing and managing paperwork in the processes that I have. So it's just a point.

MR. TAYLOR: The other thing that your HACCP plan will do is focus our inspectional effort, and what my prediction is that once you implement HACCP, you will find that our inspectional activities are focused much more on things that you would think are a worthy focus of our attention than perhaps occasionally happens today.

MR. MARSDEN: Well, I can appreciate that, but you understand since I -- what -- I believe I have a good plan --

MR. TAYLOR: I understand.

MR. MARSDEN: -- so then I have no problems with inspectors. I simply don't. I mean, any time they have -- you know, I think the other day, we had to sweep up around the dumpster or something. You know, it's all those kind of things that, you know, he looks around. He can't find nothing else, so he comes up with that.

MR. BILLY: I'm going to move on.

MR. MARSDEN: Yeah, I'm sorry.

MR. BILLY: Joe.

MR. POCIUS: Joe Pocius with the National Turkey Federation. I'm going to revert back to the original question of preapproval, and I might end up repeating a lot of what Bill Smith said, but I'm going to have to use the V word.

The way we look at this, there should be no formal preapproval process for all the reasons that John Lochner said.

The original program or any changes or modifications to it as your process changes, you may have to -- you will have to change your HACCP program to meet your process, and you may have to go -- go through a revalidation.

Now, here's where we -- we didn't really talk too much about this. It was mentioned, but the way the NTS position has been laid out is that we would have a formal appeals board, a HACCP program appeals board.

So rather than as Bill is saying then, that would go to science and technology or wherever, the appeals board should work like this. If the validity of a plan is challenged, then it goes directly to the appeals board, and this also stays -- it keeps the continuity and the expertise that Jim had mentioned earlier.

Now, if the board finds no basis for the challenge, that decision is communicated directly to the company and the FSIS in-plant HACCP trained personnel by the board, not through any other junction, and that way it's expedited.

If the board upholds the challenge, then it decides where the modification needs to be made. Now, per the proposal, when these -- as it was published, when these challenges were made, it was the opportunity there for health critical issues to be considered. If that's the case, then there was the proposal for sampling.

The board should make that decision, not the in-plant IIC or anyone else. The board should make that decision. Once the

decision is made by the board, then at that also gets communicated immediately and directly to the company and to the FSIS in-plant HACCP trained personnel. Then the modifications can be made. Then the validation process takes place, and the issue is over basically.

Now, that's not much different from what Bill Smith said, but it formalizes the whole thing a little bit more so that you know where to go, how to go, who you're talking to. You're talking to the same people all the time. They're doing the same thing for everybody around the country.

You might have one board for turkey and broilers. You might have one for pork and beef, but at least it remains the same, and it can be used as an emergency response team if you'd like in a manner that you have one right now, so they can be rapidly pulled together.

But outside of that, your validation process is the approval process. Any other preapproval system really doesn't belong.

MR. BILLY: Dane.

MR. BERNARD: Withdraw.

MR. BILLY: Ron.

MR. PRUCHA: Yes. I -- Ron Prucha. I guess too agree that a preapproval process as such should not be necessary, but I do again feel strongly that there must be some guidance given to the agency and particularly the IIC inspectors as to what an approval or validation -- to give them areas to cover when one is validated.

Another area though that I am really concerned about is the area of dispute at the plant level. They are not as you're well aware rare. They happen every day, and under inspection as it is practiced today, if there is a dispute from plant management with inspection, it generally will end up in a shut down department or product retained or stop the line or production until that dispute is resolved at some level.

Frequently, this is very time consuming, and I think under a HACCP proposal or a HACCP implementation, that cannot allow -- be allowed to continue in that manner. It is very important -- and particularly with your proposed shortened lines of supervision and control that your supervisors -- after the top to bottom structure is implemented are probably going to be as I see it more spread out, covering more territory, more plants, be less available to plants for appeals and resolution that some other very quick method of resolution be -- you know, be put in its place whether it's a board as Joe proposes or something else.

But I think the quick response and not this, you know, age-old thing of stopping production and shut the line off, and retain tons of product and do that. We've got to come up with something -- you know, something better than that.

MR. BILLY: Caroline.

MS. SMITH DEWAAL: Caroline Smith Dewaal with the Center for Science in the Public Interest. First of all, I'd just like to say that I understood Jim Lochner to support prior approval,

and I think he -- I've confirmed with him that that's in fact what he did.

So second of all, I'm not going to repeat what's in our comments other than simply to say that we did -- we have long supported prior approval of HACCP plans on the basis of increased consumer confidence. Nonetheless, knowing the current administration's reluctance to get into that issue, we've offered numerous alternatives, and I think the best of which is teams of -- teams of experts in specific processing areas or based on specific products that would travel around the country and attempt to look at HACCP plans offered advice and provide some kind of uniformity to the process of HACCP plan review.

This is particularly important for start-up purposes as HACCP is just really being introduced into the industry, and a lot of people aren't going to know what to do other than get a generic plan and stick it in a file folder in the drawer. You know, there's got to be more of an eduction process.

Lastly, I hate to do this again, but Bill -- commenting on something Bill Smith said. Following HACCP principles is not enough. It is not enough just to go in and say, did they comply with the seven HACCP principles. They're very general. They don't -- they can comply, and they can be dead wrong about the hazards, about the critical control points, about what the critical limits are.

So I really -- and I know I made this point before, but then

I hear you say something else, and we -- I am not comfortable that we're at a similar understanding about what the inspector's role is here. I mean, you really need judgment. You need to be able to evaluate it, and if the inspector can't do that, then this team needs to do it or someone else needs to do it.

But your -- it doesn't give me confidence in the FSIS program when you say things like, well, if they just follow the principles, then we'll have a safer product because it's not enough. They've got to be right about what they're doing.

MR. BILLY: Jack.

MR. HASLAM: Thank you, Mr. Billy -- working so far this week. I'm Jack Haslam, the Veterinary Counsellor at the Australian Embassy. We obviously have a critical interest in these proceedings because it will be an obligation of my organization in Australia to comply with the wishes of our major American customer which is the FSIS in that they dictate the contractual terms if you like of the specifications for the product which we supply.

The question on the table is validation of the HACCP plan, and if you'll just bear with me for a moment, I'll give you a two-minute history of where we have come from in the last ten years because I think it is germane to the debate that you are having.

We by virtue of a national government policy had to look at the issue of user fees ten years ago which did a great deal to

clarify an understanding between the functions which my agency supplied to industry and the value that industry got from the provision of those functions, and obviously, with financial pressures on both ourselves and industry, we had to look at what we were doing and how we were doing it.

Obviously, the -- and here one gets immersed in acronymology if there is any such word, but in the general sense, quality assurance was obviously perceived as the way to go, and I guess will write a dictionary on all the terms that have been used.

We realized that to make required paradine shift, we had to retrain our staff. I have degrees in agriculture and veterinary science, but I'm -- I'm not a systems engineer. I'm certainly not a mechanical engineer, nor I suspect on occasions have I been a very good personnel manager either, and I had responsibilities for the whole of the west Australian region for five years.

But what we initially tackled was a challenge to the inspectorate to recognize the paradine shift, and as a personal experience, I had 180 or so inspectors. Their average age was 54. Most of those guys had served the agency extremely well very honorably. What they did not really want to do was face the challenge of going back to school to learn chemical, mechanical engineering, food chemistry, food systems handling, and so on.

But they had to do that if they were going to respond to the challenges that we as an agency were facing. The resolution

there was to evolve a training package, and it's very pleasant to see -- to see Dr. Russell Cross here because I know that he has worked closely with us and aware of what we did on this, but we ended up offering our staff a training package of a one-year diploma course or a two-year certificate course which at completion would have offered them a substantial change in status, in salary, and in title.

And we now no longer call our staff meat inspectors. They are food standards officers which -- with a much wider range of skills than they had with the -- with the hold meat inspector training course which we gave them.

That took us from about 1985 through to 1990. We had to get the curriculum worked out. We had to get the course accredited nationally with the appropriate educational authorities, so that no only were those officers going to be of direct use to the agency, but they also would have a qualification which we hope will be attractive to industry and the wider community.

In other words, we are improving their own personal skills and marketability, and I think that that has been very successful.

In terms of where we were going in our relationship with industry, we started direct quality assurance training with the industry officers. I have been at various QA training courses where people from diverse backgrounds as railway engineering, power station management, and cement manufacturers being -- being present. The principles are the science, but the

diversity of activities, of course, makes the whole process much more exciting and interesting.

We then looked at training our line staff because we felt that they would not be able to themselves adjust to -- to the ambitions of industry unless they understood what industry was aiming for, and we then had about a two-year training program where we got small -- eight to 16 people together, half our own staff, half industry, people who had -- I think it is fair to say been protagonists suddenly had to work together on project work and so on, and again, it was very interesting to watch the dynamics there.

So having gone through that process, we had taken a critical look at how far we could push the system of -- let's call it food inspection in the general sense, but obviously, food safety is part of that. We also had a wider interest in ensuring compliance with a whole raft of other conditions imposed upon us by -- by foreign governments. They are packaging requirements, labeling requirements, shipping mark requirements, and so forth.

Those are all contained within our legislation to ensure easy access of our exported products to foreign markets. The companies were challenged to consider quality assurance systems which also embraced, of course, the particulars of food safety on the slaughter floor through the processing rooms, to packaging, refrigeration, and so on.

The current -- and I would emphasize that we regard this as a

very dynamic process. This is essentially the third generation. It's a document which I think I could put the price up and sell it quite nicely as a sideline from the amount of interest various people have shown in it, but we choose to call the program MSQA which stands for meat safety quality assurance, but be assured that it embodies quite specifically the seven principles of HACCP, and the framework is absolutely in line with the thinking of FSIS.

But to get to the point, the point in discussion is that in developing an MSQA manual, there are five guidelines here which I'd just like to point out to you for the benefit of this discussion.

Point one is that the company should contact and discuss the new system or proposed system with -- in other words, let us know what you're doing. Tell us where you're coming from. We believe that we are part of the process and that we probably -- in view of the schools and training that our own staff has have got something to offer.

Establish a time table for developing the system, and we recommend an incremental approach particularly to implementation once the -- once the plan has been agreed to, and that that is the critical point of this debate which is that when all components of the MSQA has been described in the MSQA manual to the satisfaction of the company and the local supervisory staff, the ICC to use your term, we strongly recommend that because the -- the food standards officer in

charge has personal knowledge of the plant, its activities, and so on, that he has a great deal to offer to the company in terms of helping them develop the manual.

But the manual at that point is then presented to the regional or district veterinary officer in charge for -- we use the word approval, but in this debate, we mean validation, and the process is will it work in your plant? Have you written something that you think would be -- would please, you know, bureaucrats sitting in office in Pearth with the lovely view of the river I had or is that actually what you do?

And obviously, the whole aim of the exercise is two fold. One is to say what you'll do, and the other is to comply with the legislation. It is not our business to look at activities beyond the prescribed legislation.

Having agreed that the document is workable on what we would call a desk audit, the process then goes up for a try period -- a trial period, implementation if you like. During that time, we don't offer the ratio of inspection presence. We maintain the level of inspector activity at the level of full-time inspection.

Generally, a plant would have a minimum of a four-week trial period to implement the program, and if it is working at that point, they're deemed to be up and running. Follow up from that is that we have a parallel system of audit, and we have trained audit teams who are both -- both local and brought in from outside.

We regard the -- you know, the guy from Camber or from Brisbane coming across to Pearth or whatever as being an essential element of a healthy audit process because we learn from each other, and also you don't have the danger of familiarity with the people or the plant creeping into the judgments.

But we have two formal audits a year of each plant which has a program like this in place, plus one unscheduled audit, and those audits are done according to international guidelines.

We also believe and it's absolutely essential to back this up with a strong sanctions policy and that there are a variety of penalties imposed by the agency if at audit we find defects which are rated according to minor, major, or critical. A critical defect can lead to suspension of the operating license, and we have everything in between.

The other -- if you like bait on the whole hook of this issue has been that we have tried as much as possible to align the structure of these documents to the ISO standard document so that our industry is being encouraged to develop a standards process which is -- recognized internationally, and we very much hope we'll be seen as a marketing tool for the companies themselves. Thank you.

MR. BILLY: Rosemary.

MS. MACKLOW: I know what I wanted to ask. I almost forgot. I got so fascinated with the Australian presentation.

Currently, we operate under an inspection program that says

some people think it's free, but what it really is an allocated one shift or two shifts of operation, then we pay for overtime beyond that. As we've talked today, we've talked more about the inspection system, looking a lot more like the way FDA does some inspection system, and so my question back to you gentlemen -- I finally got a real question -- is -- the other day I came to an issue with a member plant where the inspector insisted that while he had his lunch break, they also have their lunch break, and they're not going to move a piece of meat or anything else during their lunch break. It's absolutely absurd to patrol inspection system.

Is there some way in this process that you have considered reevaluating the allocation of the eight hours or the 16 hours, or ten-hour shifts, or whatever, within the structure of the system rather than hanging on to a traditional and rather archaic system where you're not going to be there every hour of every day to stand and watch? That you're going to be doing patrol inspection, and therefore, you really need to change the fundamentals on the expectations of the inspectors. Have I lost you all?

MR. TAYLOR: Not completely.

MS. MACKLOW: Not really, no.

MR. TAYLOR: I want to say something at a very high level of generality in answer, Rosemary, and then maybe Bill or others would want to add their thoughts. You know, one of the things that we think the HACCP philosophy embodies, and I think you'll

actually see some discussion of this very explicitly in one of the team top to bottom team reports that talks about better defining the distinction and role between the plants and our inspectors.

And one of the things that we need to do is separate ourselves somewhat from those plant -- daily plant operational decisions. I mean, we shouldn't be making what amount to plant, you know, operational decisions, and so with respect to the, you know, the incident you mentioned, I mean, philosophically, we're moving in a different direction than one that requires, you know, what you describe in terms of simultaneous lunch hours at a processing plant.

What that means is that the redistribution of hours, you -- perhaps others can be more helpful in it because I'm not -- you're asking the wrong person that question.

Bill, do you -- maybe we don't have an answer but Bill --

MR. SMITH: I don't think we have an answer other than what we have envisioned on -- at least for day one because that does work within the existing structure. It's working within the existing tours of duty and those rules for start up.

MS. MACKLOW: So you haven't really looked at this question yet.

MR. SMITH: No.

MS. MACKLOW: Could you add it to your shopping list, please?

MR. BILLY: It's on the list. That I can assure you.

MS. MACKLOW: Good.

MR. BILLY: I don't think we've come to any closure about how to --

MS. MACKLOW: I understand. You know, I don't expect your Boeing 747 pilot -- so, you know, this is -- you're getting some ideas out of us, but as we reform this system, you can't reform it without looking at the allocation of hours of work to your inspection force.

MR. TAYLOR: The -- I have a few mantras as you know. One of them is that we have to make the best use of our resources to improve food safety, and the top to bottom was designed to be sure we're doing that, and that has everything to do with how we deploy our inspectional resources.

So the test in the future as we make this transition for how we allocate those hours will be what's the best use of our resources to improve food safety, and if that suggests a different deployment and a different array of hours, I mean, the test is is that a better use of our resources to improve food safety? If it is, we'll do it differently.

MR. BILLY: Katie.

MS. HANIGAN: Katie Hanigan with Farmland. Back on prior approval one more time. I guess the concern I would have -- and I would be in favor of some type of prior approval but then have flexibility to be able to modify the program as your HACCP program as evolving, et cetera -- my concern would be if we did not have a mechanism like that, and we had a dispute at the

plant, and we continued to operate, and it took four to five business for a ruling as to whether or not the program was correct or not correct, what's the status of all the product that I've been making all week?

I mean, if it's an issue at 11:00 in the morning, and we're told you were wrong. The program's not correct. What about the product that was made at 10:00 that morning or 10:00 the morning prior to that? I mean, how are you going to handle all that?

MR. SMITH: Right now -- I mean, how is it envisioned now?

MS. HANIGAN: No, that's just a general comment that I'm making.

MR. SMITH: Well, again, I know this causes some problems, but again, if we have validated our program right, then you know, and it is done correctly, we shouldn't be in that situation. But if we are -- if we have a health hazard out there, then we're going to have to react to that.

And so we would be -- I mean, if we determined that a critical limit was insufficient, then the product produced under an insufficient critical limit would have to be pulled back.

MR. BILLY: Bruce.

MR. TOMPKIN: Bruce Tompkin. I'm from Armour, Swift, Eckrich, and it's our view that prior approval is an inappropriate direction for the agency to take. It's fraught with considerable difficulty. I know there will be

controversy. This process is not going to be easy. It's going to be very slopping in fact.

However, HACCP plans are dynamic. Processes are dynamic. They should be allowed to change. I think the agency stated it correctly in the proposal that it is a continuing process of approval, but I'd like to add that it's not only a continuing process for approval by the agency but also by the plant and also by any corporate oversight or, if the plant elects, by a process authority that might be brought in.

So I -- you know, if you do have an agent -- the IIC, for example, sign off onto a -- onto the HACCP plan, he's buying into it. He's a partner in it. I believe the -- I see the inspection force should participate in the developing plan. I think that's a healthy cooperative effort toward improved food safety with a common understanding of the goals and how they'll be achieved.

Now, HACCP plans basically are the plant's plan for preventing problems, and it's their responsibility to develop those plans as best appropriate for their plant, their processes, their equipment.

I think that that is generally in line with the recommendation also of the national advisory committee and recommendations relative to the role of the agency, and so for that -- for all those reasons and others, prior plant approval I think would be stepping off onto the wrong direction at this point in time.

MR. BILLY: Irwin.

MR. MUSKAT: Irwin Muskat, Jackback Foods. As far as prior approval is concerned, I certainly concur with the last speaker, and I don't see that prior approval is a function that should be necessary by FSIS.

For those people in the industry, however, that in some cases rightfully are -- have anxieties over setting up a proper HACCP plan, I have an awful lot of trust in our entrepreneurial spirit that's out there, and if not the entrepreneurial spirit, I'm sure that the profit motive will generate enough people that will find ways to develop a business of developing HACCP plans, and for a small fee somewhere along the line, they will be able to buy a HACCP plan that fits their needs and fits the government's profile.

I'd like to go back to one other thing, however. When -- I think it was Rosemary. I don't remember who brought the comment up but deployment of FSIS inspection personnel. I do understand that, you know, at this juncture, you may not be totally committed to how you want to deploy your personnel, but as a concept, let's take plants that are currently under full-time inspection at all hours of operation, whether they be TQC or not TQC plants, and let's take those same plants that are operating under HACCP plans when they're approved or when they're instituted, I should say, functioning, well-functioning HACCP plans, well under control. Would it still be in your purview to assume that you're going to have full-time

inspection in those plants?

I mean, that's sort of going as far up as you're going to go if you're -- if you still intend to have full-time inspection in those plants, it would seem to me that we're still not looking at what HACCP is supposed to be able to do for the service, and that is to be able to free up personnel where it's the most obvious place that they can be freed up. If you can't get them freed up at that point, you're not going to get them freed up anywhere.

That's a question.

MS. MACKLOW: -- I'm sorry, Mr. Taylor.

MR. TAYLOR: Rosemary, I'm more than happy to have you head me off on --

MS. MACKLOW: I was just going to add to Irwin's comment and say, if you're really buying into this whole game plan, you've got to start thinking about assigning your most valuable resources which are your inspection field people based upon risk rather than on volume, and so that's where this issue comes back, and I think that's what Irwin was getting to, and I just put some other words around it. Is that about, Irwin?

MR. MUSKAT: You're terrific.

MS. MACKLOW: Thank you.

MR. TAYLOR: And I think that -- you know, that idea, obviously, is one that has been around as one of the ideas contained in -- among the options in the top to bottom, you know, preliminary report.

Let me just deal as directly as I can with your question. We have a certain statutory framework for inspection -- understanding of which in the processing arena is that the aspiration is to have an inspector there on a daily basis, and we have a program that has been designed to do that. That's a program that, given our resource levels, is enormously difficult to meet to the letter, but that remains the aspiration of the statute and the program.

Again, there's no question about the fact that we move towards HACCP, we need to take advantage of what it does for us, to work in every way we can to make the best use of our resources to improve food safety, and increasingly within the current statutory framework, you know, we certainly intend to look for ways to deploy our resources in that spirit including attempting to set some priorities and target our efforts on those activities within any particular plant and among the spectrum of plants, target those activities that will make the greatest contribution to food safety with the resource we've got.

So that's the idea, and you know, how that is going to play out in practice is -- I mean, that's going to evolve over a period of time, but that's our objective.

MR. MUSKAT: I hear what you're saying, but it's obvious that there's going to have to be some legislative changes if we're going to even have this whole program -- an effective program, but if we're going to the point that we are at the

level of the lowest health risk in the -- in the industry, and your viewpoint as far as FSIS is concerned, and we haven't already predetermined that this is the one obvious area that the movement and deployment of personnel should be more available to you, then I still say that we're -- we're looking at a viewpoint from the service that we're almost guaranteed continued layering of inspection, continued possibility of reverting back to traditional inspection whenever that opportunity opens itself at the plant level.

MR. TAYLOR: You know, again, conceptually, we're going down the path I've described. I mean, already in our programs at PBIS, I mean, we target inspectional tasks already in varying ways with taking into account -- we need to do more of that. There's no question about it.

And so -- but again, we're at the beginning of a transitional process that has to lead to better use of our resources.

MR. BILLY: Dane.

MR. BERNARD: Thank you. Dane Bernard, National Food Processors Association. I will take at this time -- there was a question about something earlier, and then I'd like to come back to approval.

During Pat's presentation, Pat Stolfa mentioned three areas, the process, the stabilization of product, and packaging, and you talked about performance criteria for the process and for the stabilization, but we did not get to unless I missed it the performance criteria that you're looking for in packaging, and

I'd like to hear that before we leave.

Going on to acceptance, prior approval of HACCP plans -- the buzz is back -- in our comments, we expressed that we didn't think that was a good idea, and I'm going to just leave it at that because there has been considerable debate, and there are opinions, and having an accepted plan with some kind of a stamp or thumbprint or something of the agency on it has a certain appeal to it.

But I would urge you that in your deliberations over that that you think about different segments of the industry. If you're a high-volume slaughter operation, and you're doing one species, and that's all you do, it's a fairly thing because you're going to have a HACCP plan or a HACCP plan with a few nuances to deal with, and it's probably not going to vary greatly.

If on the other hand as you've heard some of our small processors who are in the business of making many, many specialty items, each one of those plans -- and here we're talking about the further processing industry and the needs of that industry versus what seems to be the target of most of our discussion which -- which happens to be the slaughter and fabrication part of our industry.

The needs in the two segments are going to be vastly different. To expect prior approval on multiple HACCP plans in a smaller operation, I think, is going to be very, very burdensome, and that needs to be considered.

In addition, Bruce Tompkin very well laid out that HACCP is a dynamic system. That's one of it's benefits, and while Bruce describes it as being messy, it can be messy, but that's one of its major benefits. That we are trying to put in place a system which will give us a much more responsive way of responding to new food safety problems.

When the next bug that evolves and Mother Nature plays another little turn on us, we have if we do HACCP right, we'll have in place a system which we can put in preventive measures and add critical control points or make adjustments in critical limits much more quickly than waiting as we have had to do with E. coli for the agency to decide what the best way to handle it is, and then put out directives to the field in how to make adjustments.

So we're hoping to put in a much more responsive system. The price for putting in a more responsive system is that we must decide how to deal with flexibility and quick change, the need or the possibility of quick change. Prior approval runs counter current to that. It's not going to be something that you can do very quickly.

So those are some of the things that I think need to be considered. Thank you.

MR. BILLY: Stanley.

MR. EMERLING: Stan Emerling. With respect to this prior approval thing, maybe if I would take the word preapproval off of it, but I think we need to know the rationale that small

businesses would have. They need a comfort level. Jim Marsden said it. Jim Lochner said it. Caroline Dewaal said it.

I really feel we need something there to assure those smaller people that they are going to be able to continue and go forward. Remove that fear factor that something is going to come down because they -- they've done something incorrectly. Whether it be the inspector, and I have a little problem with that after listening to Mr. Haslam up there say how well educated, how well trained his Australian people who are doing that and have not seen it whatsoever in -- at least so far in what has been presented for the training for the inspectors, and recognizing as I've seen from time to time that we can't even get inspectors today to take the initiative to approve simple labels because they don't want to put any onus or burden upon themselves, you -- you're really putting us in a real problem.

Those plans may never get approved, or they may be so nitpicked that they'll be impossible to be approved. I mean, you're just adding commotion unless you have a step in there that assures all of us small guys that we can go forward and do what we want to do because we're not -- we've -- we were one of the first supports of HACCP. Years back, we supported it, and all we want is a way to do it and do it effectively.

So don't take that away from us, and don't put us in trouble that we don't know how to get out of nor have the resources to overcome.

MR. BILLY: Joe.

MR. POCIUS: Thank you. I've heard a number of -- well, to Stan's point, the approval process as we see it is the validation process, and Mr. Haslam pointed out they use approval, the word, in Australia. Here, we've been referring to it as validation.

When I refer to prior approval as a formalized process, I'm referring to the blueprint formalized preapproval, labels preapproval. We would not like to see a system wherein we submit our HACCP programs to Washington headquarters, wait in line until they're reviewed, and then return back to the field, and then maybe someday, you know, after we're passed the deadline for having implemented, we may be able to try and do it.

So the validation process would take place in the plant, and in this case, the IICs who would work with you as Bruce Tompkin had mentioned, that would be your stamp of approval if you will.

On the other hand, the IIC gets the opportunity to challenge that. In the case of a challenge whether it be an original HACCP program or a modified, it then goes through that appeals board, and as we've looked at this appeals board, we looked at it in terms of a very rapid turnaround, not a four or five day process. You know, a 24 to 36 hour process. It may be wishing for a lot, but if that's all that they do, then that should -- it should work.

Now, the question earlier was raised, what happens to product in the meantime. As we've looked at it, unless it's a -- a flat-out plain health critical issue, the process shouldn't stop. That's a decision for the appeals board to make. You haven't failed anything. You haven't failed a critical control point. You haven't -- you failed a HACCP program. You're just going through a validation of a new -- a new system. Until you fail, why should your product be -- be controlled?

MR. EMERLING: If I may respond -- would it be all right?

MR. BILLY: I --

MR. EMERLING: I won't if you don't want me to. I'm just saying, I'm not looking for an elongated process like you're talking, Joe, but you also have to understand the differences in the way that business is run.

I would suspect that most turkey producers work the inventory. They can have product there. A delay of a day might not make a difference, or four days, to get the thing back or two days, but in smaller plants, it's instant business. They take orders at nine and ten o'clock in the morning to delivery before noon, and so we need to be sure that there is a process that's approved that goes -- that doesn't -- we don't it elongated, but we want the safety net of knowing that at least what we're doing is okay.

MR. LOCHNER: I want to jump in here. Really, what I'm asking -- and I agree with what Bruce Tompkin said. In theory and in practice, that's the way it should be, but the key is

the first shot eliminate as much variability as you can of opinion. That's the primary reason to go after it.

And I think a review panel -- it would be -- it would be an adjunct to the training of the inspector in charge and company both if you had this review. Now, you can call it an approval, or you can call it a specialized review because I think both the company and I do believe I know how to write them, and I do believe that most people do because they're not that complicated to write.

But when people start second guessing, and I worried about the IICs trying to do a good job, and some who think that they know and miss it, and try and eliminate the variability between plants, and we have to recognize reality. It does exist on uniform programs that are submitted today.

I would say that maybe we throw out all prior approval on grade labeling programs, net weight, and economic issues, and put all the focus for the next two years on really thorough reviewing and feedback reviewing on this, on HACCP safety related issues.

MR. TAYLOR: Let me just make one observation that flows off this discussion if I may because Tom has -- we have a couple more agenda items here yet today, and this has been a very helpful discussion, and I appreciate the back and forth and the getting out some of the reasoning that underlies people's views on this issue because this is a very important concrete issue which we need to make a decision, and our thinking is open.

We do have lots of resource and other practical reasons as well as philosophical reasons for being resistent to formal prior approval. On the other hand, we are thinking about various options that I think address some of the concerns including whatever you call it, having immediately accessible to the in-plant inspection program an identified set of experts whose job it would be, you know, to promptly back that inspector up and participate in resolving those in-plant technical scientific issues that relate to whether the judgment is that a HACCP plant is valid or not or even is being verified adequately.

But where there are technical issues that require, you know, real expertise that is beyond what we would normally expect of an in-plant inspector, we know we have to have a resource like that immediately available to resolve these. We don't have the details of that worked out, but I think even again if you'd look in the organizational plan, the organizational structure preliminary report from the top to bottom, I mean, there you'll see in that context we're thinking even as we speak about organization. How do you -- how do you place the experts to back that program -- back that in-plant inspector up in a very immediate way independent of a cumbersome chain of command and layered process for resolving disputes.

So this has been a very helpful discussion on this issue. Thank you.

MS. MACKLOW: Mike -- use the PQC models for the last twenty

years is anything to go with?

MR. BILLY: I'm going to move along. I know there were some other flags up earlier. We do want to cover this item C on the agenda in terms of FSIS role in facilitating development of HACCP plan, and Pat's going to highlight some of our current thinking in that area, and then we'll have some discussion on that, and depending on time, I'm going to try to wrap it up because I'm told that some time soon, music is going to start back here over in the -- so we'll have to be a little flexible, but -- I -- try your luck. Pat.

MS. STOLFA: Pat Solfa, FSIS. I wanted to highlight some of the -- what might be viewed as technical assistance activities on which the agency has been working for a while. These are in various stages of development, and they will result in products that will be available to anyone whose institute, to any company that's interested in using them although we do anticipate that they would be of principle interest and benefit to smaller companies.

As we committed to in the preamble to the proposed regulations, we will issue generic models for each of the -- each of the process categories that we've identified. Actually, I believe we have nine process categories, and we're working on 12 generic models because within the slaughter process category, we would anticipate more than -- more than one model, and in a couple of other categories, we have more than one model.

The generic models are -- will replace the generic models that were developed by the agency some years ago through the workshop strategy. We believe those generic models are not as useful as they might be in terms of providing -- providing a good example of what a -- what our ideas are and regarding a hazard analysis. That's a principle are in which I think those previous models were -- were perhaps not as well developed as they could be, and since that's a really important first step, we wanted to have generic models that were more useful in that regard.

We're also trying to make the generic models a little more user friendly. We have completed -- we intend to do some of these internally because we have some capacity to do that, and we hope to be able to contract for some external development of models, but we have completed the first generic model for the raw ground products, and we have put that into peer review. Just late last week or early this week, that went into peer review, and that peer review will include both a scientific peer review and also a peer review by potential users especially small establishment users.

So that's the generic model plan that was basically outlined and referred to in the proposal, and I just want you to know it's going along. We're working away, and we expect to be able to meet our commitments in that regard.

In addition, for some time, the agency has been working on a handbook for -- or guide book for HACCP implementation. Again,

particularly designed to facilitate work in small establishments, and we will be proceeding to ask some small establishments to try and use it and tell us whether or not it's any good.

We're about at the point where that's what needs to happen. We've been fussing around with it and dividing it up and, you know, sort of reapportioning it in different pieces, et cetera, but the truth is that what we need to know is whether or not it's of any use to anybody who might be interested in using.

So we're making some arrangements to ask people to give us some feedback on that. In addition, we will attempt to do a hazards and controls catalog, similar to but probably not quite the achievement that the FDA hazards and controls for seafood is, but we are working on a similar kind of document to be applicable to meat and poultry products so that there will be a resource to which people can turn to be able to identify the common hazards as well as some of the more common controls, and that is under development.

We are in addition aware of some externally developed potential technical assistance materials which might be useful to people, and that is, these aren't things that we did, but we don't particularly need to do them if what these other people have done is valuable, and we can get some agreement from them that they might be willing to let us use it in some way.

And -- and at the top of this list here really for us is a how-to video that was developed some years ago by Agriculture

Canada, and it might be a nice sort of companion piece to a well-developed small plant handbook. This piece that Agriculture Canada developed is -- at least in the views of those of us who have looked at it -- quite a useful and piece and might have some -- some particular utility for people who want to have in addition to or other than just written materials, they might want to have some sort of visual communications.

And we're also aware of some other videos that might service the same purpose, but again, this is a matter of our finding out if the materials are useful and then seeing if we can enter into some arrangements that might permit us to make these widely available at relatively small cost.

In addition, we've been aware for some time of some computer programs that have been developed to assist companies in establishing HACCP plans, and in the two cases that we're familiar with, we have had at least informal contacts with the developers of the programs who would have some interest in our working with them to be able to customize those programs so that -- that they were reflective of current food safety standards as applicable to meat and poultry products.

And if we felt that we could get some feedback from companies, that that would be a useful thing to have. We could put some resources into doing that. The way the programs are now conceived is more general and more reflective of overall food safety standards, less -- less useful in the specific

terms of food safety regarding meat and poultry.

And so that's an area in which we -- we just try to keep track of what those people are doing. We have not put a lot of resources into that ourselves because, frankly, we've had some other things to do, but if that would be a useful vehicle, it's certainly one that we'd be willing to explore.

So those are what we would -- those are the technical assistance materials that are under development in the agency, and as I say, slowly but surely we'll be coming forward, and we'll be making those available for some initial review as well as for use by people who might be interested in them.

In addition to that, we -- we are willing and I believe the agenda alludes to our willingness to entertain proposals or discussions. We don't even usually have a formal proposal process right at the beginning. At least discussions with usually I would say institutional as well as individual companies, individual small and medium sized companies to undertake some demonstration efforts, and I'll describe how one of these -- the one we're working on right now happened.

I -- I took Tom's place and made a speech to some people in North Carolina that included the North Carolina Meat Processors and was actually facilitated by a person from the extension service who has ongoing relationships with the North Carolina Meat Processors Associations and with more broadly, all of the meat processors in that state.

And during the course of and before and after that meeting,

he indicated that he would like to know if there was any way we could -- we could continue to work with them and we could continue to -- his particular interest is in training, and I said, well, you know I've got all these technical assistance materials. Maybe you could use them for training, and in the process, you could give me some feedback as to whether or not they're any good, and so started a relatively simple idea for what we hope will be some demonstration plants of a small size in North Carolina which will have support from the North Carolina extension service.

I believe -- and I don't want to speak definitively on his behalf, but I believe he has made contacts with the public health infrastructure in his state and the -- as well as the meat inspection program, and he has an industry group that is willing to facilitate some meetings and get the word out, not just to their own members, but to anybody within the state that would be interested in it, and what I'm hoping will come of that is a series of demonstration plants through which we can have small plants that -- that will demonstrate certain aspects of this process of implementing HACCP and be willing to share their experience so that we can disseminate it and use it so people will overcome what I think in at least some cases might be fears about things that might not be entirely justified or at least fears that we should be able to address if we put our heads together.

And this -- the possibility of doing this in more than the

state of North Carolina is certainly open. We haven't made any general announcement of that. I believe we should do that in order to -- in order to be fair about all of this, and -- but I think that we would have the resources to do that, and that may be a useful thing for us to do if some other people are interested in it.

So that's where we are on these things.

MR. BILLY: Comments? Steve.

MR. KRUT: Is that pilot project or demonstration project in North Carolina, are you setting these up with a vision of just seeing how they operate or to demonstrate how they operate, or are you actually looking at measurement of effectiveness?

MS. STOLFA: I expect that they won't all be the same. In this particular case, and we haven't -- we haven't finalized the plan and a series of objectives as well as time frames which we would like to do in any instance. In this particular case, we're principally focusing on I would say training and technical assistance delivery.

And so what we would be wanting -- we would be wanting to get out of that particular demonstration is -- is feedback as to whether or not the training that basically the extension service and the state are sponsoring, supplemented with our technical assistance materials, resulted in sufficient HACCP expertise that companies could in fact move ahead to develop their HACCP plans, and so that's what we would like to demonstrate in that state.

At least that's our vision right now, and again, I -- I don't want to act like this is totally finalized when we really are in the sort of back and forth and discussion, and everybody hasn't had a chance to put all of their ideas on the table, but that's what our interest is in that particular case.

Now, there's opportunities for a lot of things to be demonstrated it seems to me. That there can be -- there could be demonstrations about how -- how small plants could accomplish a good hazard analysis given that they don't have a whole lot of scientific and technical resources that are immediately available to them.

I think that might be something that would be fruitful to look into. I think that we -- we might be wanting to look into the issue that I know you have brought up on many occasions, and that is, what can we do in instances where we have plants, small plants that are producing multiple products in small volume.

What can we do about modifying plans in such a way that it might better accommodate that or trying to get all of this into one plan or at least one framework that would make it work a little better.

We are not setting out in this series of demonstrations to -- to try to answer or to try to answer the question is HACCP effective or is it not effective. That really is not our objective. We have some more -- we have I would say more practical immediate kinds of objectives that we'd like to see

accomplished in these demonstrations.

MR. KRUT: Okay. That was kind of getting to what I was I guess asking about. I think earlier you heard some reference to -- I think the Jackback had nine different HACCP plans. Somewhere in the proposal, I believe the reference was made to a category of similar products which would identify potentially how many HACCP plans would be needed based on what categories the products were considered to be different.

We still don't have that feedback, and that's why I think it's very important that, you know, I know we have timelines we've got to work with, but I think we've got to demonstrate effectiveness of HACCP in a small plant environment before we mandate it.

Secondly, I think the -- I appreciate the idea and the concept of looking at a -- maybe an overall generic HACCP concept for a small plant where they do make a lot of different products. Maybe 40 percent of them go through the smoke house, or 25 percent of the hundred different products go through the grinding system.

So I appreciate that, you know, the department is interested in pursuing that, but I hope we do take into account measurement of effectiveness.

MR. BILLY: Okay. Marsha.

MS. ECKOLS: I'm Marsha Eckols with the National Association for the Specialty Food Trade. The members of the association are primarily small companies with make small volumes of

products, and many are making multiple products.

There are two issues that are probably of paramount importance to them with regard to HACCP. One is the extension or the extra time in order to comply. Perhaps as someone mentioned earlier, letting some of the larger companies try first and experiment and then having the smaller companies follow.

One of the things that we've found is that small companies want to be known to consumers as having the same quality and safety of products as the large companies, so they will as quickly as they possibly can do the same things that the large companies do.

They will try to do it before any deadline that they're given, but they do need extra time. One of those -- one of the reasons for their requirement for extra time is the financial one. If the figure I heard earlier today of $27,000 for a HACCP plan for one product is true, for a small company making several products or processing several products, that cost becomes prohibitive for them.

That brings in the question of training materials, support of various kinds so that the small companies can do all that is necessary to comply as quickly as possible, but also so that they can understand what is going on. It is impossible for a small company to do what Oscar Mayer suggested by saying we are ahead of you, FSIS, and can you catch up with us?

A small company cannot do that and needs a lot more time but

has the same desire to produce safe products for consumers. So that the recognition of the need for the extra time, the financial burden on small companies, and the need for training support and assistance are of paramount importance to them. Thank you.

MR. BILLY: Joe and then Bruce.

MR. POCIUS: -- get this thing on. Hello --

MR. BILLY: Okay?

MR. POCIUS: Okay. Thank you, Tom. Pat, two quick questions. First was I think I missed what the peer review was for the generic model. If you'd go through that again, I'd appreciate it, and the second question is yesterday I mentioned that we had developed a model HACCP plan for our industry. Would you accept that and put it through your peer review if I get a better understand of what that is and use that? I think that would help underwrite what we -- our efforts in the past, and I think we might be happy to help you out in that case, too?

MS. STOLFA: We -- first of all, just let me answer the peer review. We are sending the -- as I said, we are looking to about a dozen generic models, and we are asking that either -- if they're developed in house or if we develop them some other way that they be put through a scientific peer review process, and so we have sent our first model out to a couple of highly qualified people for a scientific peer review.

In addition, we would like there to be a review by the

potential users, especially small companies, so that as part of what we're calling a peer review process, we would -- we would be thinking of sending our generic models to small -- a couple of small companies and just asking them whether or not they communicate effectively, whether or not they can follow them, whether or not the -- you know, there's a certain amount of tabular presentations. Whether or not that's useful and understandable.

There's -- literature, there's a bibliography and a literature review probably as part of the hazard analysis, and so the question is is it useful for the people who are likely to be using it.

In terms of our being willing to look at your model, we're pretty hungry for models, and so -- and we'll also very poor, so we would be very glad to take whatever people offered to us and see if it meets what -- we kind of have an idea of what we're looking for, and perhaps if it doesn't, that you'd be willing to do some more work, and I think we could work that out.

MR. POCIUS: Yeah. Well, back in 1991 when we did this work, I did ask some people from the micro committee to look at it, so we kind of went through that process anyway. Though, that was probably different people and an earlier era, and it has been distributed to the industry, and it's specifically for a mid sized or smaller member who couldn't do it in house himself.

So I think I'll pass that through some of our members and see how they feel about it, and I will get back to you. Thank you.

MR. BILLY: Bruce.

MR. TOMPKIN: I'm Bruce Tompkin from Armour, Swift, Eckrich. I have been following this evolutionary process, of course, for a number of years relative to HACCP, and the weakest link at this point in time is the lack of availability of good generic HACCP models.

They -- if you look at what's available in the literature or through the previous USDA pilot study that was conducted -- there was a pilot study, but also they brought together groups to work on the cooked sausage and the ground beef and so on. There really is not acceptable as HACCP plans today.

I have been involved with a very small group of people to generate HACCP plans. It's a very time-consuming processing, but I would recommend at this point that they are so important, it is, of course, best to work from a draft. It's better to modify a draft than to create something, but it's also very helpful to do it across a table where you can talk about what's going on.

A -- to send a HACCP plan out for peer review is one step that's a good idea. That's one step towards that process, but there's so much that can be gained in a very short period of time to have a small group of experts in hazard analysis to sit around and actually go through that process.

The national advisory committee is an option. However, they

move very slowly. I know. I was in that process. In six years, we got two out. One on beef and one on broilers. What you're looking for and what we need at this point in time is a collection of very good scientifically based and critically reviewed HACCP plans.

MR. BILLY: Lou Gast, you had your flag up earlier?

MR. GAST: Thank you, Tom. I particularly thank you for giving me another opportunity since I wasn't here at the last call, but I had agreed to wait my turn, and I waited so long I had to leave before my turn was called.

In any event, just by way of background, I spent in excess of the required amount of time with the Department of Agriculture, and when I met that and also the requisite age, I left the department in 1986 as the associate administer of FSIS, and I have since been -- had the opportunity of joining the private sector, and I'm known among -- fondly, I hope, among those in this area at least as one of the beltway bandits.

But my purpose in asking for time at the microphone was initially to support two folks, Stanley and Steve, in terms of their views that a dispute resolution process was necessary. Since I asked that time, there has been a number of other people, and I support all of them, Jim Marsden among them, and anybody else who either has said there needs to be consideration given to this, and those who may not have said it but feel it.

It's not enough in my view for the agency to say, we're using

an appeal process. Everyone has a right of appeal. The appeal process in my view is cumbersome, and in many cases, it does not work. In order to work, and I -- by the way, I don't have an idea for a better one except this -- in order for any appeal process to work, it's got to start at the agency top. There has got to be agency commitment to accountability on the behalf of inspectors, supervisors, and management within the agency.

And if you think that there -- that that's not necessary because you haven't had that many disputes to resolve, I would suspect that if there was an effective way to do it, there would be disputes to resolve. Today, many people will not go through the process for a number of reasons, not the least of which is they may -- the feeling at least -- that they may win a battle but lose a war.

So I encourage you to give that consideration and dispute resolution, just as we're attempting to do here through this process. If in the best of all worlds, this dispute resolution process at the end of the day on the 29th resolves all disputes and a final regulation is issued, you will have disputes regardless of that after that date.

MR. BILLY: Okay. Paul.

MR. KORODY: Just getting back to Joe and the turkey issue, if there was a generic program for turkey slaughter which the department signed off, if an enterprising turkey plant just adopted it without modifying it to its circumstances, would then the inspector there be obligated to accept that?

MS. STOLFA: -- generic models -- generic models are not really designed to be sort of taken off the shelf and then submitted. They really do need to be accommodated and modified to suit the circumstances in a particular plant, and it seems to me very unlikely that -- that one could just take a generic model without modification and have it sort of -- have it adequately reflect what was going on in the plant because the way the -- the way the plan gets individualized is by -- is by -- is by modifying it to reflect exactly what the processes and procedures and practices are in the plant.

And so I don't think that -- I mean, that's certainly not what they're designed for. I think it would be somewhat difficult to make it work that way, but Bill can talk about what he's going to do about it.

MR. SMITH: Well, I agree with Pat's thinking, and that when we use the V word, that we would probably say that that is not a validated plan unless we see that the effort to do the hazard analysis or particular to that plant that the monitoring activity is particular to that plant. The records being kept are particular to that plant, and the plant verification activities again are particular to that plant.

MR. BILLY: I'm going to wrap this up. The -- I appreciate everyone's patience and input. The paper for tomorrow is available out on the table if you haven't picked it up already. We will start tomorrow morning at 9:00.

(Whereupon, the meeting ended at 6:07 p.m.)

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Docket No.

U.S. DEPARTMENT OF AGRICULTURE, Washington, D.C.

Place of Hearing

September 14, 1995

Date of Hearing

We, the undersigned, do hereby certify that the foregoing pages, number 2 through 175, inclusive, are the true, accurate

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