UNITED STATES DEPARTMENT OF AGRICULTURE
WASHINGTON, D. C.

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PATHOGEN REDUCTION/HACCP RULE :

A meeting on the above-entitled matter was held on Wednesday, September 27, 1995, commencing at 9:02 a.m., at the U. S. Department of Agriculture, 14th and Independence Avenues, S.W., Washington, D.C., before:

Thomas Billy, Chairman
Daniel Glicman, Secretary of Agriculture
Richard Rominger, Deputy Secretary of Agriculture
Michael Taylor, Acting Under Secretary for Food Safety
Bill Smith
Pat Stolfa
Bill Gaines

P R O C E E D I N G S

MR. BILLY: There are some procedures I'd like to follow. I also had mentioned that some of the arrangements we have available and briefly go through and look at the agenda just so that everybody has a sense of what the day will be like, both in terms of time frames and subject matter. The purpose of these meetings is to have a substantive and focused discussion and dialogue among all of us on the agenda items. The agenda items were developed based on a process and I'm going to work very hard to keep us focused on the agenda items. What this is about is an open and balanced exchange of views and so as I have a sense of the discussion I may well call on some people to elicit a different point of view if I have a sense that that is appropriate or needed. But for the most part, what is important is that people having a view, having some input on a particular aspect of the issue at hand should participate in the discussion and talk to each other about concerns, points of view, ideas, that kind of thing. I'm going to work hard to keep us generally on the time frame in terms of what we've got scheduled for today. I'm going to encourage people to stay on the specific topic. There are some new people here that I don't remember at the first three meetings. That's terrific. You don't need to have a prepared statement or to explain -- you know -- your credentials. We're all here interested in the same issues. If you do have a prepared statement the record is open. The dockets office is right here in this building. You can provide that to the people at the table out here and they'll make sure it gets into the dockets, into the record, and will be considered as part of our analysis of all the comments. The comment period is open till the 30th of October. Once you make a point I encourage you not to repeat it. As you can see, there are a lot of people at this table and around the room and it's important that we maximize the time we have available to stay real focused on the key and substantive issues that we're trying to address.

There are some instances where some may feel that the solution to a particular issue is through a legislative change or through legislation. The Secretary has announced his plans to hold a separate workshop next month that will, in particular, focus on that question about legislative change so if that's a point of view that you have and you want to provide that kind of input I would encourage you to take advantage of that workshop and participate in that and you'll find that that whole area will be fully aired and addressed as part of that

overall workshop that's planned.

In terms of the process, the first three days of meetings I generally follow the procedure that's used in many different areas but particularly in the international arena where if you want to get recognized to speak you hold up your name placard and I keep a running list and I think that worked quite well, particularly for the first two days, but both based on some comments I received, the third day of meetings when we focused on the micro testing and standards we tried to modify that a little to have it more open in terms of people feeling free if someone makes a point and have a question about it or a comment about it to jump in and make that comment. What we'd like to do for today, in particular, is to encourage that kind of dialogue and exchange. That there's going to be some trade-offs so we all see the number of people sitting around that have a very keen interest in these areas so we need to be respectful of each other and it needs to be a dialogue and let's keep it flowing. To the extent that occurs, then I'm going to back off a little bit in terms of speaking in a structured sequence. But if it's not going well or if people still aren't able to get in and make their point then I'll use combination of the two to make this work so I'm going to play it a little bit by ear to see how it works but the idea is that we want all of you to have the maximum chance to provide your input to this dialogue, to this process so we'll just see how it goes and if I have a sense that we need to make an adjustment I'll do that and I'll let you know.

The agenda for today is focused on three fairly specific more technical areas -- carcass cooling standards for red meat and poultry, anti-microbial treatments in slaughter plants, and sanitation standard operating procedures. It's hard to judge how much time we need on each of those so as a general matter, sort of a guideline, my thinking is divide the day up into about thirds and we'll see how that works. Now, we can be flexible. If we need to keep talking about one particular area or issue we're prepared to do that. But that's a sense of the timing and how -- you know -- in terms of making sure we get through these important issues today.

If there's an issue that comes up that's on the periphery of one of these or new issue that one puts on the table we do have the flexibility of adding that to the agenda for the 29th so if you have a thought like that raise it and -- you know -- we'll address it. We'll figure out to deal with it.

I want to remind everyone that with respect to the 29th we did carryover two earlier agenda items. The first relates to the agenda item for the first day, September 13th, Part D Timing, and we decided both because of the discussions that day and subsequent days that it made more sense to have that timing discussion at the end so that is added to the agenda for the 29th. In addition, with regard to the discussion on FSIS oversight of HACCP, Part C dealing with insuring compliance with HACCP requirements, and there are several billets under that, we similarly carried that over to Friday and will be part of Friday's agenda. So our intention to have a discussion about those areas as part of Friday's agenda.

We do have an overflow room. It's 4347 here in this building. It's one of our conference rooms. It's on this backside. Just go out and up to the fourth floor and it's down one corridor -- third corridor. So if you're interested you're welcome to take advantage of that room. We also have rooms available if someone wants to caucus and have a meeting among some number of people to talk about an idea or whatever so if you need that let the people at the desk know and they will make arrangements for that.

Are there any questions about the arrangements, how we're going to proceed? Okay.

We'll run for about an hour and a half this morning till about 10:30. We'll take about a fifteen minute break. We'll resume again, probably run till twelve or a little after twelve and then take an hour for lunch. Lunch is immediately available. Come back, get started in a similar manner. If it becomes clear to finish today's agenda that we need to go a little beyond 5:30, our scheduled ending time, I intend to do that. I want to work hard to complete this discussion so we need to be a little flexible on that end of it. That remains to be seen whether that will be necessary or not. Okay. So with that I'd like to introduce Mike Taylor, the Acting Under Secretary for Food Safety, who has some brief opening remarks.

MR. TAYLOR: I just would like to add my welcome to all of you and express my appreciation for the effort that is represented by the presence of this many people in the room on these issues. We found the week before last that the three days of meetings to be extremely valuable, very good substantive discussion, and very helpful to us. I hope on some of the issues having to do with the manner in which, for example, we would plan to inspect under HACCP I hope there was some

progress made in clarifying what our current thinking is on those issues, but overall for us it was an enormously valuable three days and we look forward to the next three days being equally valuable. We are moving into some very specific substantive issues in the near term intervention category and we have had enormous amount of helpful comment on these issues which we've evaluated and we've now in the papers that have been distributed reflected some -- you know -- some openness in considering alternatives, in particularly the vein of seeing some of the objectives of these proposals could be accomplished through performance standard oriented approaches and enhanced flexibility. But we really are interested in getting down very specifically to -- you know -- pros and cons of what we proposed and alternatives so we can move our decision making process along.

Secretary Glickman is keeping very close tabs on our deliberations. He will make every effort to be here as much as he can. He has got today some phone bill and budget reconciliation commitments that are very substantial but he is in very close touch with our deliberations and will be here as much as he can.

I don't know whether there was a calculated design to disorient us by changing the seating arrangement. I am only slightly disoriented. With Rosemary there, I'm sure she'll be there for the three days, I will soon have a comfortable reference point and by Friday it will be home again here in back of the cafeteria. I look forward to the next three days very much and I'll turn it back over to Tom.

MR. BILLY: To --

MS. MUECKLOW: Tom, with all due respect to Mr. Taylor I understand the meeting room was rearranged so that you would look better on camera on that side.

MR. TAYLOR: We had a lot of rearranging to do to pull that off.

MR. BILLY: We probably need all the help we can get.

At this point I'd like to get started on the first issue, carcass cooling standards for red meat and poultry. Pat Stolfa is going to very briefly just highlight the paper that's been made available to you. Some of you may not have had a chance to study it. She'll emphasize certain aspects of it and then we'll open the dialogue.

Pat.

MS. STOLFA: Thank you, Tom. As Tom mentioned I'm just going to quickly run through the key points that are summarized in the issue paper on this topic. As you know, the proposal contained very specific

requirements for carcass cooling and the objective of those near term requirements was to insure that all establishments are controlling the growth of pathogens through appropriate use of cooling. We received substantial comments of substantial number and a great deal of technical information from the comments and in a general way I don't believe that there was any very significant disagreement with the use of carcass cooling to achieve the objective. There were comments that suggested that there might other ways of accomplishing this objective. For instance, there might not be -- some people suggested there might not be a need to have carcass cooling requirements as a near term objective; that they could be encompassed in HACCP plans. We received a number of comments on the details of our specific proposal for carcass cooling. Such things as whether internal temperature, external temperatures were more appropriate, whether or not the specific temperatures we were suggesting were achievable routinely or whether they would present difficulties for particular establishments or people producing particular kinds of product. There were some comments also that spoke to the issue of workers' safety as well as worker comfort in situations where strict carcass cooling requirements as we were proposing were being carried out. So that was the main flavor of the comments and what we've done since looking at the comments is to try to advance our thinking on how we might be able to accomplish the objective on which I believe there was general agreement but perhaps provide additional flexibility so that some of the details that people found troublesome would not be the problem that they were represented. And I would direct your attention to the three general options that we have laid out here on the second page of the paper. They do represent our current thinking as perhaps other approaches to accomplishing this objective.

The first one could be characterized as fairly consistent with the kind of regulations we now have and that is we might still propose that a specific temperature be achieved within a specific amount of time. However, we might change the temperature rather than proposing the forty degrees or fifty degrees model that we had in the proposal. There might be some other temperature which would be more satisfactory. And one model that is sort of out there, at least in the international arena, is the requirement of the European Union which is a specific temperature requirement. So that's one kind of approach which might resolve some problems.

Another kind of approach is represented by option two and that is to establish a carcass cooling performance standard expressed as a maximum level of pathogen growth. For instance, one could say that we're not going to tell you exactly what temperature you have to achieve but between the time the carcass leaves the kill floor and the time that it leaves the establishment we don't want there to be any more than one log of growth and that would be an example of the kind of performance standard that we're thinking about as part of option two and part of a performance standard approach.

Option three represents a different kind of performance standard but it's still sort of performance standard and that is we might say at the end of the process, perhaps at some point in the cooler or some point where we had some data collected perhaps as a result of our baseline studies, we're going to establish a level of organisms that has to be met. And we don't care how you get there. We think that smart people will understand that cooling -- carcass cooling is an important tool for achieving that particular performance standard which could be expressed as a certain -- perhaps as generic E. Coli or perhaps as some sort of a pathogen target and we will count on you to manage your process and to control your process so that you can consistently achieve that standard. This also is the kind of performance standard approach and probably provides us a substantial amount of flexibility and may be attractive.

But at any rate, in summary, those are the three options that we're now thinking about.

MR. BILLY: Okay. So given that, let's start discussion and who would like to go first?

MR. MAY: -- --

MR. BILLY: Yes.

MR. MAY: We're lacking a volunteer.

MR. BILLY: Okay. I forgot to mention one thing, Ken. I'm sorry. Before each of you speak, when you speak, be sure to say your name because this is being recorded as part of the record so it's important each time that you state your name.

MR. MAY: I'm Ken May and I represent the National Broiler Council here today. We have no problems with the SOP's as they're written now. In fact, they're almost a step backward in the case of broilers as far as getting our product temperature down. We chill in a liquid medium and we can reduce the surface temperature in a matter

of minutes and we can reduce the internal temperature of the product down below forty in quite a short time.

We do have some concerns in two areas on this for the same reason that we can get the internal temperature down quickly because we have a thin product, a low product profile. We also have problems within the plant of product temperature arising during the processing in the plant. We may have it below forty but as we cut up and debone and do other things to get it in the package we inevitably have a rising temperature and we think the Department needs to seriously consider that. It doesn't happen for a very long period of time because the product moves through rapidly but we just have no way to keep it below forty unless we made all of our processing rooms forty degrees fahrenheit. We can't keep the temperature down. It goes up. Current regs allow up to fifty five degrees during process and we hope that the Department would seriously consider some sort of a rise in temperature for thin profile products. A good example is chicken wings which is very, very thin and you hang a chicken on a line, by the time you get to the end of the drip line it might have started at forty and you may already be fifty degrees in that wing because it's so thin.

One other thing that we had a concern about was the way it was written up about receiving product into a plant from some other plant and what would happen if it is above forty degrees fahrenheit. Currently the inspector and our quality assurance people look at product temperature as long as the product is still cold and it smells good, there's no obvious odor on it or anything like that, the product can go ahead into process. And it's a little bit unclear what the regulation, the way it's written right now, would do with a product if it came in above forty degrees fahrenheit. That's not necessarily dangerous in any way but it leaves a little uncertain as to what would happen to it. And we think you need to give some additional consideration to that. Thank you.

MR. HUSKEY: Good morning. Len Huskey with Swift and Company. I would just like to suggest that with respect to the use of a temperature criterion that because of the normal process variation that we experience that we look at that as a statistical process control approach and with that approach that we recognize that variation and not have an absolute hard line at forty degrees is that is ultimately the number of whatever that number may finally reside. Thank you.

MR. PRUCHA: Pat has -- Ron Prucha. Has any thought be given to rather than a carcass cooling temperature for various species to establish shipping temperature? I don't think that there are many plants that keep product around any longer than necessary. It's the -- the object is to move it out and move it into the channels of commerce and I think possibly a shipping temperature for fresh meats that it cannot be shipped below forty or forty five or whatever is chosen might be a better approach than to try and come up with individual carcass temperatures or whether it's a surface temperature or internal temperature or various things like that. It might take care of -- you know -- a number of problems.

MS. STOLFA: I think that has been tested and I would say that in general an alternative like that fits in the -- within the conceptual framework of the first alternative that we laid out. I mean we're just trying to put some examples here. Obviously, we don't have all the details done but people certainly have -- that kind of approach has been considered as a part of this structure of options.

MR. BILLY: Any other views on this idea that was just suggested? Jim?

MR. LOCHNER: Jim Lochner with IBP. On that specific subject, I think, Ron, there is very specific shipping temperatures proposed. The question is, are they attainable in the case of beef carcasses at forty degrees in turnaround. That is a problem. Depends -- the real problem I really want to get at though is that as proposed in the regulations, we're not dealing with one temperature issue here. We're dealing with multiple temperature issues. I'll limit my comments to beef and pork. But, specifically, we're talking about carcass surface cooling rates which, if you use sophisticated and proper equipment, are not attainable but the real problem was the proposed regulation didn't specify where to take that temperature. In beef carcasses, an enormous surface, when you measure it first, the thin muscle areas, we get the forty degrees. If we measure the thick portions in the shoulder clod area or in the middle of the round and if you measure the surface area appropriately with either multiple readings on the surface or in a case, I happen to use infra red technology, you'll find that a percentage of the surface area is above fifty at five hours is enormous but variable. So there's some huge problems there, but on the carcass surface issue, I didn't think that the data presented in the proposal supported the action. And if you look at carcass chilling rates

versus models demonstrating microbial growth or go get real data you'll see that there's two different things totally. The real data will show that in reality carcass surface is going into a hot box called zero time and coming out twenty four hours later there's nearly a log reduction in total plate count. There's no substantial -- there's no detectable growth in, for example, E. Coli species or, therefore, probably pathogens. And if you look at some of the model data, and particularly I thought Cargill's comments in their filed comments were excellent demonstrating the why behind that. But the carcass surface issue is only one of many that we need to deal with but I don't see in your options that you've really addressed what you're going to do there other than by saying if we look at, for example, demonstrating less than a one log increase. I think that if you research that that's not even practical. I mean we're not talking in that realm. I think we have to come up with carcass chilling parameters to some degree but I'm not exactly sure that I'm going to sit here today and recommend what they are. But if you look at some data, some of which I've personally generated and I thought particularly, again, the Cargill data, you'll see there's no practical difference between fifty degrees in five hours and fifty degrees in ten hours.

But on the other surface -- other temperature issues, hot pack off all and hot boning. The point is that -- the mega point I'm going to make here is there's no incremental gain to food safety relative to the cost. I have no problem spending money to improve food safety but I have a huge problem spending money with no incremental gain to food safety and I think that area as to be researched very, very thoroughly before we're going to codify regulations on carcass surface temperature and others.

MR. TAYLOR: Can I ask a question? This is Mike Taylor, USDA. What are your practices? I mean what criteria or objectives do you attempt to achieve in your operations?

MR. LOCHNER: Chilling beef carcasses. Really we specify cooling tons of refrigeration per volume of product. In our case, we look at like two to three head per ton of ammonia refrigeration and that's -- you start going by designing your hot box or your initial carcass cooler chillers, typically called hot boxes. You go by design criteria and then you really monitor what's going on relative to all the parameters associated with the equipment -- suction pressure, volumes, etc. We can mechanically monitor the process, which to me

is much more adaptable to a HACCP approach rather than trying to go out and hunt and pack with a huge variation in carcass size looking at trying to find the best or worst case. So we start with really design criteria. And that design criteria is to balance a variety of things. Carcass surface chill is one. But in the case of beef carcasses, as well as pork to a lesser degree, but to some degree, we try to balance also quality into that aspect and then final temperature chill rate which is an important aspect when you're coming back and you're going to have to rely on people to separate tissue. I think it's important to understand that beef carcasses particularly have an enormous temperature variation at twenty four hours after chill or twenty four hours after slaughter in a chiller. You try to target to get to deep round temperatures in the fifty five to sixty degree range and your thick meat areas will essentially potentially be frozen at that range or close to it. They won't be frozen; they'll be in the thirty two to thirty to thirty two. So you have that much temperature variation which you have to worry about -- temper actually to try to drive the round down to less than forty five before boning and actually bring some of the surface temperatures or some of the deep tissue temperatures of the thin areas up so that you do not have ergonomic problems when you go into the boning room. I know it was emphasized to some degree in, I think, AMI's comments and I know it was in our's as well that the ergonomic standards are what we are concerned with because the colder the tissue the more force required to do the boning and so, again, the design parameter comes back to try to balance those. Again, we're dealing in a case of beef carcasses with an immense variation -- anything from five hundred pound carcasses up to almost a thousand pound carcasses and, in some cases, they go much wider. But it starts with really design parameters in the hot box design.

MR. TAYLOR: Thanks.

MR. BILLY: Fellow on the end there.

MR. NEESE: Tom Neese from North Carolina. The subject is sow carcasses. It is entirely conceivable to bring sow carcasses down to fifty degrees in five hours with no problem. If you take a six to seven hundred pound sow carcass -- sow -- you have great difficulty bringing that carcass down to forty degrees in twenty four hours -- point one. Point two, we're a cold process which means we operate both cold and hot but we are cold process. There are times when we take a sow carcass approximately an hour after going into the cooler, roll it on to

a reefer that is twenty degrees, move it twenty miles to another plant, roll into a thirty five degree cooler, two hours -- three hours after that it is thirty two degrees. And, yet, you're telling us we cannot move that carcass until it is forty degrees or less. And, yet, we are doing a better job when we do it that way than if we let it sit for twenty four hours. It's one day younger. We will operate with no inventory. And what we produced today goes into the grocery store tomorrow. Thank you.

MR. BILLY: Can I ask you a question? In the paper in terms of the agency's thinking there are two or three options there that two of which kind of move away from the specifics of what was proposed that would address that in both that concern you just raised. Are any of these options more attractive to you in terms of accommodating your needs?

MR. NEESE: I'm not technically able to answer your question because I'm a generalist and not a technician.

MR. BILLY: Okay. Thanks. Jerry?

MR. LEISING: Jerry Leising with Cargill. Just to follow up a little bit on carcass chilling, some of Jim's comments from IBP. We have done quite a bit of data collection on carcass chilling and just to begin with, I think the loading of a cooler is very key but I think the other element that plays a big part in cooling is spray chilling and we haven't talked too much about this. The heat transfer of spray chilling is about forty or fifty times faster than air chilling and it's a key part of the process. In the theoretical models that were put out by FSIS I think it was assumed there was a linear cooling curve that was occurring there and the reality is that a carcass cools expedentially -- in other words, from ninety five degree surface temperature to about sixty five degree surface temperature. That happens in about two to three hours time and, therefore, it allows a lot more additional time then to go from sixty five to fifty. And, so, the total chilling curve may be ten hours but what we really accomplished by chilling so quickly on the surface early in the chill cycle is a lot of time to get to fifty and so the bacteria really stay in the lag phase most of the time. And, so, in that ten hour chill curve we really end up with less than a log growth. Certainly -- you know -- we believe that chilling is a critical control point in the HACCP and this is all part of a HACCP program and so we're really designing a HACCP then for that product and that plant and that situation. Certainly each plant is quite

different. Each cooler is different and temperature monitoring equipment and procedures to obtain the data are very critical and they need to be clearly defined. Air and data collection can result in making some wrong decisions. Having a computer program where we can put this data into and integrate time temperature very easily will be essential. And I think it will make it uniform for the industry. Auditing function would become much easier. It's very difficult to get these temperatures in the middle of a beef cooler. We have to apply the surface probe early in the process when it's entering the cooler. And, so, -- you know -- I think we're going to have to have a very defined method of data collection.

MR. EASTERDAY: Hi. My name is Ron Easterday. I'm with John Morrell and Company and we're a small slaughterer that kills approximately nine to ten million hogs a year.

One of the problems we have with the proposal is based on our equipment situation. I'd just like to review that with you for a second. You may not be aware of it. There are very few systems in the United States. We have a Danish type system that basically is a deep chill system. It's a minus seventy degree cooler with high wind velocity that we kill the carcass in the morning, seventy five minutes into the system it comes out of the system and the outside surface is completely frozen. The internal temperature at that time is still approximately eighty five degrees in ham muscle and slightly lower on a shoulder muscle. The cavity in that surface basically -- the rib, the loin, the backbone, the neck bone area -- basically frozen. When we take it into a hog cooler basically we do a reverse system where we try to equilibrate the outside cold temperature and drive it inside and get a temperature down to a realistic temperature. But we cut hogs now in about six and a half to eight and a half hours after they're slaughtered so we're killing this morning, we're cutting this afternoon or early this evening. To do that, our cut temperatures will range anywhere from forty one degrees to about forty six degrees and occasionally you get some higher. So to live with a forty degree internal temperature form cut, I mean the system doesn't allow. Okay. We take and cut it at temperature because of the ergonomic issues. We want to reduce the stress on employees -- their backs, their arms, various other reasons. Also, we feel that we have very good controlling system and once we bone or cut or separate this carcass we have numerous other systems that chill that meat rapidly. We use

nitrogen, we use CO2, we use blast freezers, all types of other systems, cooling rooms. We use outside storage if we have to. But our corporate policy is, which we adhere to every day of the week, is we don't ship a pound of meat out of our plants unless it's less than thirty degrees fahrenheit. On our boxes we specifically state to the retailer and distribution trade in our sales brochures that we want them to store our pork at twenty eight to thirty two degrees because that's the longest possible temperature for shelf life. Okay. We try to provide our retailers with information, microbiological charts that show bacteria growth and everything, because we are concerned about it and we sell millions of pounds of meat a day. Our customers demand maximum shelf life. The only way I can get that is the rapid drop in a temperature but I can't get it when I got to the cut floor. Okay. Thank you.

MR. BILLY: Debbie?

MS. BERKOWITZ: Debbie Berkowitz from the United Food and Commercial Workers Union. I just wanted to address the issue of worker safety because our members work in IBP, Excell, Cargill, Morrill, and the poultry industry. And I wanted to make sure that whatever you do on temperature that you be very careful not to substitute one set of problems for another. That the issue of worker safety is very legitimate in meat packing. That they have the highest rates of these crippling carpal tunnel, tendinitis disorders than any other industry that meat packing and poultry are number one and number three. And that one of the issues way back when we looked at what's causing these problems in the industry, besides the fact that it's incredibly repetitive and forceful work, was the fact that in many packing houses they were cutting frozen meat and the meat itself may not have been frozen but the fat was frozen and that was as good as cutting frozen meat. And one of the big agreements we worked out with the big companies. and they're all sitting here today, was that our workers would not have to cut frozen meat. Right now our packing houses run -- you know -- when the temperature goes below forty five degrees we hear it at the union. They want to raise it. The people can't work. It's too cold. Work is too repetitive. And they're getting hurt. In terms of the meat coming out, I called a number of our packing houses and I can't stress enough that I think you all should go out to these houses and measure the temperature but when I told them that -- you know -- they had to meet an internal temperature of forty degrees

and the meat had to be forty degrees every single one of our stewards said we're going to be cutting frozen meat. And I don't think they meant the meat would be frozen. I think what they meant is the fat would be frozen.

The other thing we're very concerned about is they thought that the companies, in order to meet these regulations, if they couldn't quick chill them enough down in the coolers, because some companies keep it only for twenty four hours before we're cutting beef, that they would lower the floor temperatures down and that would be a terrible thing to do to the over hundred twenty thousand workers in the meat industry and the two hundred thousand workers in the poultry industry. It is very cold in those places. Right now on the hamburger lines in most places they run thirty two, thirty five degrees. It is freezing in there. You know -- when the temperature goes below forty degrees it is freezing in those plants and -- you know -- they wear sweat shirts, they wear double gloves, they wear coats. And so I really stress that it truly is a legitimate issue and I'm truly hear to say that we also believe that the meat's got to be safe and we can't be more in your court on that issue. But you really need to take into the consideration that these are legitimate issues that the meat industry is bringing up in terms of worker safety.

MR. HODGES: Jim Hodges with the American Meat Institute. I think you can see by the previous comments that there is a wide variance in the type of chilling systems that is used. The same chilling system for pork operations does not apply to beef because of muscle quality issues. The same issue doesn't apply in beef that applies in poultry. That is why we recommended to the agency that these time temperature requirements along with all of these other near term initiatives be incorporated in a HACCP program. By the very definition of your HACCP program it allows the flexibility to establish the parameters that are needed to achieve a certain end product characteristic. Cooling is -- the cooling parameters that are used in the plant is a balance among a variety of different factors. It's a balance between getting product cooled quickly, to retard bacterial growth. That is balanced off against muscle quality cause if we freeze product too quickly we get muscle quality problems in terms of cold shortening and toughness. That's balanced off against worker safety issues that we've heard Ms. Berkowitz adequately describe. So it's our recommendation -- our strong recommendation -- that these time

temperature requirements be focused within the context of a HACCP program and that allows the flexibility for the Mr. Neeses and Easterdays and the Lochners to set their systems up in an appropriate way to achieve the desired results.

MR. BILLY: Okay. Go ahead.

MR. TAYLOR: This is Mike Taylor asking a similar question. Just to sort of be sure you're clear on where our current thinking is. The comments have been fulsome in laying out, as some of you have done this morning I think very helpfully, some very specific processing situations where our proposal is just flat at odds with the way you're doing business. You're doing business in a way that is very aggressive in terms of -- you know -- meeting a high standard when it comes to cooling carcasses from the perspective of -- you know -- our collective food safety objective and so we've got to deal with that sort of variation because it makes no sense, obviously, to try to have -- mandate a single method of achieving -- you know -- a carcass cooling result. And that's why we've put on the table the notion of performance standard alternatives because, I guess my question for Jim is, if -- you know -- whether we do it now or we do it at the time of implementation of HACCP if we say -- and, of course, I think everybody agrees -- that carcass cooling would be a critical control point in a HACCP plan, but your suggestion is, leave it to the sort of flexibility of HACCP to take the system into account and tailor something that fits within a particular plant setting. Again, philosophically, that's what HACCP is and we're very in since with that. I guess the question that we grapple with, recognizing that there are a wide variety of operations, some of which are more aggressive than others in addressing the cooling issue, how would we, if we were inspecting a HACCP plan in a cooling -- you know -- in a critical control point, how would we judge the adequacy of it? I mean what performance standards can do for us is give us some benchmark for judging whether a critical control for cooling is adequate? Is there a performance standard that is -- that can help -- you know -- give us some basis for judgment whether any specially tailored approach to carcass cooling is adequate?

MR. HODGES: I think there is a number of approaches that could be used. Jerry's suggested some microbiological modeling with computer systems. I think the point is missed though that it is necessary to set a performance standard on cooling. Why don't we set

a performance standard on every single critical control point? That's a ludicrous kind of suggestion from my point of view. What you have to do is to allow the flexibility of the plants to establish the program that achieves whatever the desired end results that you may -- that the plant wants to achieve. You can't do that by setting individual performance standards on isolated items. Many of -- there's people in the room here today that have hot boning operations. They're in the package probably less than an hour. That is one scenario. The others goes in a wide range of times and temperatures and to set a one size fits all requirement through a regulatory standard when we have none today when there is no documented evidence that we're going to substantially improve the food safety parameters that we've got I think is probably adding a lot of cost and regulatory burden without achieving substantial benefits so the point I'm making is, there should be flexibility there. And the HACCP program, by its very definition, provides that. When you come in and validate that HACCP program you ought to have the technical expertise to judge whether or not those cooling systems are in fact adequate. Obviously, if you have no cooling system it's probably not adequate.

MR. TAYLOR: It's the definition of adequate that we need to come to grips with.

MR. HODGES: I guess what I'm suggesting to you is that adequacy is determined by the results, not by how you get there.

MR. BILLY: Rosemary?

MS. MUECKLOW: I'm not clear that the carcass cooling system is so broke that it needs this major injection of what really is a command and control system over and above HACCP. I think Jim has made some excellent points here this morning. I would suggest that we have some other participants in this meeting here today who have met international standards and to gain that recent OE experience I had in the other hemisphere. I know Dr. McKenzie's here. We have some excellent Australian people here. Might we see if they would venture into the water with us and tell us how they have dealt with this in order to deal with this on an international basis. Might this be helpful. I just hate to see us get bogged down into designing requirements in this country that are going to be out of since with all of the other trading partners that we do business with worldwide.

MR. BILLY: Karen?

MS. BOLTE: Karen Bolte with the National Consumers League.

We've been hearing a lot from industry and I think one of the things we have to remember is that this is a near term measure so to improve food safety obviously temperature cooling requirements are going to be critical control point in the HACCP program but this an interim measure -- what we can do right now as we're moving to a HACCP system so we feel that there needs to be cooling standards. This is a basic principle of food safety. And the cooling standards -- I mean we agree that -- you know -- the cooling standards have to be achievable. It has to be something that everyone can reach and certainly that the standards should be set so that they're not resulting in an increase in the bacterial load on the product and also that they don't create worker safety hazards.

MR. BOYLE: To that point, Karen in a general sense, is absolutely right. There should be time and temperature requirements or absent specific temperature requirements which will vary from product to product, plant to plant, there should be another system in place such as a one hour from slaughter to package hot boning operation where you achieve a temperature reduction that is suitable to control bacterial growth in the operation. You are generally correct. There needs to be controls in place that control the growth of bacteria from the point of slaughter to the point of packaging before it leaves the plants per subsequent distribution.

The fallacy, however, is two-fold. The fallacy of your premise, as I see it, is two-fold. One, that the way to achieve that bacterial control in a plant is to establish a uniform system of temperatures in certain time frames across the industry by species. It does not have to be that consistent because there's a lot of variations in the plants and the products and the species. And the reason that actually I think we are here today, and Mr. Secretary, why you are here today and have been here for three meetings in the past few weeks and probably portions of tomorrow and Friday as well, has to do with the fundamental difference that I think the industry has and HACCP experts and advocates in general have with the two-tiered approach that FSIS is taking in this rule making. Nobody disagrees that HACCP should be mandated. Well, actually, I guess there are disagreements. We don't in the American Meat Institute. We think it should be mandated in all 8,000 plants. No one disagrees that this is the best process control approach that we have today. No one disagrees that as a plant develops its HACCP program and establishes critical control points, those

points may include time and temperature requirements depending upon the plant, the product, and the process. They may include the use of anti-microbial treatment or a combination of treatments that together or in tandem work more effectively than one alone. No one disagrees that as part of the verification step that is an inherent and essential part of any HACCP program you might conduct microbiological testing for process verification purposes. No one disagrees that all those elements should be part of a HACCP program. And the review of whether that HACCP program is adequate and is being administered efficiently is the role that we see FSIS assuming as we move towards this new inspection system.

The disagreement here is whether or not you take a few of those critical control elements of a comprehensive HACCP program and you extract them out of that HACCP development process and you impose them in the near term in a uniform way that does fit the way the industry operates on a species by species basis in the really arbitrary belief it is going to have an impact. There is evidence that if you control the temperature and the time during which you reduce the temperature on raw product you control pathogens, you control bacterial growth. But there is no evidence that dictates or suggests or even objectively implies that fifty degrees uniformity in every beef carcass on the surface within an hour and internally within twenty four hours, forty degrees, is the best way, the most effective way to get there. There are a lot of variations there. And so the fundamental difference that we are struggling with here during the three meetings previously as well as later this week is why does the agency believe that we need to extract major portions of a HACCP program out of the development of the HACCP regulation out of the implementation phase of the HACCP implementation -- I mean the HACCP program -- and impose them within ninety days in a uniform, and in many respects, arbitrary way instead of allowing the industry to develop those time temperature requirements to determine to best use of anti-microbial treatments, to determine the appropriate role of microbiological monitoring within the plants, within their HACCP programs and then subject that to the review, the monitoring, and the verification by FSIS. And as long as we have that inconsistency between HACCP being plant-specific, product-specific, process-specific, and the near term mandates that are in the initial proposal, we are going to have this tug that is preventing us from moving as quickly to a comprehensive

HACCP program, as I think both of us would like.

MR. BILLY: Caroline?

MS. DEWAAL: Caroline Smith Dewaal, Center for Science in the Public Interest. We've heard over and over again that if consumers just cook their food, or if consumers didn't thaw their food on the counters, or if consumers didn't use improper handling that resulted in cross-contamination, then consumers would prevent food-born illness. And so there are all these standards out there for what consumers need to do and if consumers fail to exercise the proper control then consumers are creating the problem. The question, I think, that we're dealing with here is, are there similar standards for the industry can exercise to minimize the hazard of their product? We all admit that the products are potentially hazardous if handled improperly. But the question is, what can the industry do and how quickly can you do it to minimize that risk to consumers? To my mind, it has to do with the margin of error that is in any product which is going to consumers. What is the pathogen load and if there is a cooking error or a handling error what's the margin for error and are you going to protect the consumers enough with your practices? I'm hearing here a sense that, well -- you know -- we're all different so we can't abide by one standard. We can't abide by one system. We can't all meet this requirement. And I guess my reaction is that you expect consumers to all meet requirements and I would ask that the industry do the same.

I think Karen's clearly articulated the approach that's been taken by the consumer and public health community on this issue. I'd just like to comment briefly on the options which USDA has proposed. The third option represents a traditional FDA approach. It is, in my mind, very difficult to enforce. You are chasing that horse after they've left the barn. You're trying to prove that is a product is hazardous and then back up to a control problem. So I think that you really need to look at that as -- and that's what I hear from Jim Hodges and Patrick Boyle -- this idea that -- you know -- well, let's just set a standard and then let the industry figure out how to meet it. I guess my thinking on temperature controls is that this is fundamental -- the food safety. If you can't agree within the industry, and I understand there are differences between products, but if you can't agree that what a basic standard for temperature control in the industry is then I mean we are in much worse shape than I think we really are.

The other thing I would just like to add is that we need an

approach. We've been hearing today from some probably processing operations with really premier systems -- -- you know -- and I have no doubt that many of these companies have really gone through a very extensive system to develop very, very excellent cooling systems and they know the capabilities but I also think that the Department needs to look at what approach is going to work for the other companies and for companies that may need one standard or may need -- they may need to upgrade their equipment. They may need to get refrigeration equipment or some standard because they're operating more on the margin and they are not taking the cooling requirements that we all know is important to food safety as seriously as they need to. So, look at an approach that not only works for the top of the line companies but for the rest of the companies as well. Again, we have supported the use of a single or a set of criteria and we continue to support that although we hope that the scientists will give us an indication of whether there's more flexibility. If forty degrees isn't the right number maybe there's another number to use.

MR. BILLY: Rosemary made a suggestion earlier that perhaps if any of the international representatives are willing to join in and indicate their approach in this area it might add to the dialogue so why don't we seen what -- you know --

MR. BIDDLE: My name is Robert Biddle and I represent the Australian Quarantine and Inspection Service. We have lodged comments jointly with your industry in relation to this specific aspect of temperature requirements for carcass cooling. We have submitted experimental data that strongly supports your second option, mainly to establish a carcass cooling performance standard expressed as a maximum level of pathogen growth. We have been able to demonstrate, we believe, in our submission that there are a variety of temperature and time conditions which provide an equivalent microbiological outcome. We have measured that outcome against no more than a 1 log 10 increase in E. Coli numbers. We have been able to show, we believe, that a variety of processes with quite different temperature time criteria can make this outcome. These processes may be hot boning, what we call warm cutting, traditional boning, and a variety of other measures. Where these processes are viewed as a whole to the end point of packing this outcome can still be achieved. There may be a transient rise in surface temperature, a deliberate process for conditioning the hardness of fat because of workers' safety

considerations, there may be a transient rise associated with the loading and unloading of carcasses moved between establishments for boning or cutting. All these standard industry practices can, we believe, be accommodated within an overall safety standard.

The philosophy we have long followed in my country in my regulatory service is one of specifying outside limits of temperature and time which satisfy this condition while providing flexibility for industry to perform alternative approaches which have this same desirable outcome. And we believe that we have been able to produce sufficient data to demonstrate that this is achievable in practice and provides tight safeguards.

MR. BILLY: Andrew?

DR. MCKENZIE: My name is Andrew McKenzie and I'm from New Zealand. Seeing that Rosemary has raised the issue of her recent OE and how we do approach these problems in countries like our own, we're heavily involved in exporting to quite a range of countries. We owe the success, if you can describe it as that, of our system to command and control and that's a fact, but I don't really think that's the way to go. It's a way of achieving results. We think that under the system if you actively inspect and enforce you can achieve results equivalent to HACCP. But it's our belief that until you do get the responsibility for food safety firmly on industry's shoulders and I think that's where HACCP takes you that you don't make any progress. We found in our own country with temperature controls and time that we already running into all sorts of problems because just as you've heard around this table you get all sorts of processes and variations and people in the need to compete against each other are coming out with innovative and creative ways of boning and chilling, and so on, and so on, and so forth, and even in our country we've run into problems trying to run a command and control program on the sorts of operations that we have.

Obviously, in any meat system in terms of food safety temperature is critical and somewhere along the line you're going to have to address that. The objective's got to be to prevent the number of bugs going on the carcass to start with and then once they're there and you're going to get them there because you don't think you can produce meat without bacteria unless you get into some sort of intervention like radiation, that you need to move the product through that -- -- temperature would -- -- quite rapidly and I think that as

Bob Biddle from Australia indicated the sorts of work they're doing, the sorts of work we're doing in New Zealand, it's about modeling on generation growths and that type of thing, and I think that if we were starting again we would very much take the approach that it would be about the numbers of generations or logs or whatever you call it, but incorporating the whole thing into a HACCP approach and I think from that point of view, although you're looking for a quick fix, and I think that's a problem you have today that we'd be very much following the approach of the AMI and the commentators around here that have actually talked about having a full blown HACCP program, including temperature controls are met. Thank you.

MR. BILLY: Are you right on this point?

MR. HODGES: My response was -- I guess I was going to ask Caroline a couple of questions to promote some dialogue. But I think the gentleman from Australia and New Zealand is adding credence to our original premise that the one size fits all command and control kinds of regulations don't work. The question that I have for Caroline or Karen is, one, how would you structure a regulation that would read so that everybody could have the flexibility needed in order to achieve the best results, and, secondly, what scientific evidence do you have that says the proposal which you support is going to substantially improve food safety?

MS. DEWAAL: Jim, what evidence do you have that defrosting a roast on a kitchen counter is going to put your family at risk? And, yet, we tell consumers all the time that they can't defrost food on their own counters. I mean the -- I don't have a specific scientific study that I'm going to cite for you that says that refrigeration is important. I think it's fundamental and I think that there is probably a lot of agreement around this table that you need to refrigerate to minimize the increase in pathogens on the meat. I mean -- you know -- this -- I don't know where your question's going. How would I structure a regulatory program? I think that you could structure a program which provides a basic standard and then provide an opportunity for companies who can achieve that standard using a different mechanism to give them the option to put to the agency that they could use a different approach. It may be a mixture of option one and option two but I think that you do need -- I think it's too much to ask for the smaller companies to say -- you know -- you've got to prove system result in less than a log increase when some of these

people may not know what a log increase means. I mean I hope they do but some of them might not. So I think you need a basic standard of -- you know -- forty or forty five degrees wherever it comes out but then if companies can achieve a performance standard using a different mechanism they might be able to get an exemption from the standard. That would be one approach.

MR. BILLY: Karen, did you want to say something?

MS. BOLTE: Well, Bob, did you want to --

MR. HAHN: Bob Hahn from Public Voice. I was just wondering how the EU was able to come up with a one size fits all temperature for red meat. They seem to be able to do it. I also wanted to say that on the second option I wonder how you can insure compliance with a maximum level of pathogen growth given the variability of pathogen concentrations and pathogen levels between carcasses and between different parts of the carcass?

MR. BILLY: Someone on the European question first? Yeah, Bob?

MR. BIDDLE: Yeah. Robert Biddle again. Based on the European question, they have in their legislation a seven degree celsius deep muscle temperature requirement. That is flexibly interpreted. They recognize the equivalence of hot boning, warm cutting practices, and so there's not an absolute measure as to they way they apply their legislation.

DR. TOMPKIN: Bruce Tompkin from Armour Swift Eckrich. The question is whether we have a system that's currently broke or not and that's been raised and also how do we compare with our trading partners. And from New Zealand we just heard that there are two issues. One's contamination and the other is preventing growth.

With regard to beef, which seems to be the carcass meat that's lowest to chill, we do have some data that we can really refer to assess whether, in fact, the system is broken and whether we need -- to what extent we need to move forward rapidly with some changes. The idea of a cooling guideline or requirement is a good idea. And certainly the rate of chill is important but the National Baseline Study for Beef which was done to -- from October of '92 through September of '93 -- was intended to represent the beef industry at that point in time. It was statistically designed and two thousand some samples were collected and analyzed. If you look at the data from a microbiologist's point of view, yes, certainly some pathogens are present and so on, but the question is, did growth occur and with

regard to E. Coli, the biotype 1, there are 172 samples that were positive out of the 2,000. Ninety eight percent of those were equal to or less than a hundred per square centimeter. That is not multiplication. With regard to the coliforms there were more positives. There were 340 and ninety six percent of those were less than -- were equal to or less than a hundred and for the total plate count there were two thousand of those samples contain full plate count -- that's expected. Ninety three percent were at ten thousand or fewer per square centimeter. To a microbiologist, I think those numbers are favorable as they reflect the industry and, in fact, they indicate that multiplication during chill is really not a significant factor at this point in time. Preventing contamination is important and then you follow that up with rate of chill. But I suggest on the basis of these data that current industry practices for beef are adequate to prevent the public health concern of multiplication of these pathogens.

And I think it might be helpful to put into some perspective the forty, forty five, and fifty degree fahrenheit. That's been discussed but from a technical point of view, we did use the USDA ARS statistical model that's been developed to predict growth rate for a number of pathogens. This is the one from Philadelphia, of course. With regard to E. Coli 015787, arimonus (phonetic sp.) which is a hypothetical pathogen at this point, your cenianorocoletica (phonetic sp.), listeria monostogenese (phonetic sp.) and salmonella species, if you were to go through those models that have been developed you will find that there was a half log increase in twenty four hours for listeria monostogenese at fifty degrees fahrenheit. None of the other pathogens multiplied. There was no log increase. So the question is, what is the margin of safety that we have? Fifty degrees is -- if you also consider there's quite a bit of data in terms of lower -- the lowest temperatures at which these pathogens multiply. Profringens (phonetic sp.), it's lowest level is fifty four fahrenheit. That's really not a problem in that respect. Staph is forty four. Listeria goes down to close to thirty two fahrenheit. That's one of the most tolerate of low temperatures. Clostrate profringens (phonetic sp.) will not multiply below ninety fahrenheit. E. Coli 0157 cuts off somewhere around forty five fahrenheit. And salmonella can multiply down to forty one but most can not grow below forty five -- below forty five. Now, if you look at those, those are the lowest temperatures at which

they can multiply but the -- you have to consider the rate -- the lag phase. How long does it take for the bacteria to get adjusted and then begin to multiply? In the case of E. Coli 0157 at fifty degrees fahrenheit the lag time is two days. Well, you think you kill a carcass and you slaughter it, and you put it in a cooler, you're going to get it out of the cooler within two days unless it's over a weekend. So really the fifty degrees -- I think that the data that are available on the pathogens, their capability of growth or no growth, the baseline study all suggest that the system is not broken currently. Yes, some guidelines could be helpful. We could make some improvements. We should set some cooling rate requirement. How that will be done I'm not sure. But in terms of forty degrees and forty five degrees, I would suggest those are GMP's. They're not food safety numbers. When we really start talking about fifty degrees before you start getting into food safety concerns and then you have to consider time at those temperatures. Thanks.

MS. DEWAAL: Could I just respond to the question that was put to CSPI regarding our scientific basis for our position? If you have seen our comments, Jim Hodges, on page 41, footnote 48, provides the scientific studies which form the basis for this position.

MR. BILLY: On this point?

MS. MUEKLOW: Tom, could Bruce explain for those of us who are not microbiologists, just for the record, what a lag time is, please?

DR. TOMPKIN: Okay. a lag time is the time it takes for a microorganisms to become adjusted to its environment and then to initiate growth or multiplication. And as you take a -- go through the slaughtering process, yes, there are bacteria on the outside as well as in the intestine. And then as the animal is -- goes through the slaughtering process some bacteria will get on to the carcass, whatever type of carcass it is, and it's going to take some time for those bacteria to become adjusted to that new environment -- you know -- basically they need water, food in order to multiply, and then the rate at which multiplication will occur is dependent upon temperature. So that's the lag time and then once they start to grow then it's a matter of all those conditions that enter in. And the cooling -- the scientific basis for the cooling requirement really is well written but it was limited in its ability to build into that estimate or assessment the lag time -- the time it takes to go through that adjustment and as you can see fifty hours is what it was and by their

data and it's mentioned in here -- two days to go through lag at fifty degrees fahrenheit. That was not considered in this -- in their scientific assessment. So they were limited. So it's very understandable that they could reach a suggestion that we have to go this fast but in reality the data don't support that.

MR. BILLY: How about Paul Clayton and Joe Pocius, Dave, Eric, and Dell. Let's get through those and then we'll have a break. Oh, Jim, I forgot you, Jim. Sorry. Paul?

MR. CLAYTON: Paul Clayton with Montfort. Let me just echo that my company also believes a lot of the things that my counterparts have told you from IBP and Excell relative to the way the organisms grow and things happen in our plants. They're similar to our plants as they are their's. Likewise, we have concerns about worker safety and ergonomics also. We also believe that the cooling requirement should be within the HACCP program. Let me add one more thing to that and I'll belabor this issue much more. But to what Bruce was saying that as a scientific community tells us more and more about how to chill carcasses I think you all can understand that the system really isn't broke but that we actually will advance it. We will make it much more dynamic and better system because cooling is a basic requirement we have to do for these products. It's a perishable product. We have to sell it and of utmost importance is the food safety that has to be in it and which we don't want to deter anything away from that because of a failure in that system so new technologies in temperature is going to happen. Just in the last couple of years we've seen advancements. So it has to be a dynamic system and we believe it fits best within HACCP programs.

MR. HANKES: Jim Hankes from Illinois Meat Processors, small plant operator. I sit here as a small plant operator and kind of wondering how obviously this is going to affect us small operators across the country and a lot of us, I guess, one point that hasn't been brought up is the fact that our products go into our hot boxes, they're chilled, and then they typically go into our holding coolers where you've got a reduction in temperature and then they go on to further processing and probably we carry inventory longer than obviously the major companies do and I don't know of the USDA when it was looking at the different options -- you know -- had any data to look and see what kind of effect -- you know -- this type of operation would -- you know -- what -- how the temperature controls in this type of situation

would affect the meat quality or surface. I know specifically last week I was checking temperatures and I can reiterate what everybody else has said in the room, that these temperatures aren't obtainable even though I'm more fortunate than a lot of small processors and we have a newer plant. We use big four hundred pound size carcass or eight hundred -- nine hundred pound carcass weight cattle. You just cannot obtain this. We just don't have the luxury of being a thin product. The safety thing I'd like to hit again is the fact that these temperatures are difficult to work in. Shoot, they're people around this table today shivering. Let's drop the temperature thirty more degrees and see what happens to them. And then -- you know -- there's just so many things here that I think it's important -- and Paul really hit on it -- the fact that the industry is taking giant strides in the last couple of years and I really feel that we're rushing into this thing not knowing what we're doing. That we're headed off the cliff a little bit and on the blind side. So I guess I'd like to caution us here because we start mandating time temperature requirements without really knowing what it's going to do for us and I think we could have problems.

MR. POCIUS: Thank you. Joe Pocius with the National Turkey Federation. I was going to apologize for shivering while I spoke but I thought maybe the agency was just putting theory into practice today.

MR. BILLY: Well, it's actually a theme.

MR. POCIUS: We should have more of these, Tom. It seems to me from the discussion that I've heard this morning that there's one fundamental issue that has to be answered and it can only be answered by the agency and that is -- the issue is one, should there be mandatory cooling parameters and the other is, should these not be in HACCP. You have one. Does it preclude -- does it go headlong in arguing the other. And my question to you is when this was published, they're published as near term initiatives. I'm sorry, it's interim initiatives. They've since become defined as near term initiatives. Completely different things in my mind. If it's an interim initiative that indicates that there is an end point. Before we get into -- and I reserve the right to argue some of the feasibility issues depending on your answer -- but before we go any further we need to know whether these are going to have an end point. When HACCP kicks in will these then be withdrawn or will they be maintained as mandatory throughout? It's an important part to know.

MR. TAYLOR: This is Mike Taylor. Joe, that's a very valid and important question. Again, what we're grappling with is given that cooling is an essential element of a safe production process when it comes to raw meat or poultry products what is the basis upon which a system -- you know -- of both production and regulatory oversight could be devised so that it is some measure of accountability for meeting that element of the responsibility plants have. That's a generic question we're asking across the board and given that cooling is an essential element of a food production process we're looking to see how it is that we can, whether on a near term basis or whether HACCP, have some way to assess whether what any particular plant is doing is adequate when it comes to carcass cooling. There's no question that HACCP provides the intellectual framework for doing this systematically and -- you know -- carcass cooling, again, I think, wide consensus will be a critical control point in any HACCP plan for a slaughter facility. But even so, again, we're grappling with the question of when we look at a HACCP plan and we look at the critical control for cooling how do we judge its adequacy and there are various ways -- options for doing that ranging from having prescribed the critical control all the way to simply being concerned about whether the finished product is meeting some performance standard with options in between, including having a performance standard for the critical control. But any way, the issue for the immediate present is not whether the plants frankly sitting here for the -- you know -- have adequate cooling systems and we know what you do and we know that you're in many, many, many cases way ahead of what we propose, in fact, and certainly operating in a way that -- you know -- is sort of at the state of art. And our objective with the near term element of this was not to sort of push the companies that were current at the state of the art, beyond the state of the art, the issue we're grappling with is an environment in which we know because we go in plants every day of a wide diversity of performance levels. I mean there are some plants that aren't currently -- at least we have no way of being confident that they are meeting their carcass cooling responsibility because in contrast to poultry, though we have articulated in guidelines some standards or criteria, we have nothing -- no basis upon which we who inspect can judge other plants are meeting their carcass cooling responsibility and so really the thought behind the proposal was -- you know -- how can we, in the near term, because

carcass cooling is so essential, have some practical means of insuring accountability for all plants in meeting their responsibilities. And, so, is our idea near term or long term. Obviously, when we're moving towards HACCP and I think the model in which we will deal with this critical control as well as others is the HACCP model and so it's certainly conceivable that an approach that makes sense, pre-HACCP might not make sense under HACCP. One option, obviously, is to time this accountability with implementation of HACCP. We don't draw such a fine distinction, I guess, between the near term and HACCP. Our issue, our concern, our question is given that carcass cooling is essential, given that there are a wide variety of performances out there, I mean how can we, for beef have some, for red meat have some way of insuring that plants are meeting their carcass cooling responsibility. I mean that's sort of simple. The proposal is one -- was one attempt to sort of lay out an approach and clearly we need to assess that but our objective is to have some measure of accountability for meeting this element of responsibility.

#2 MR. POCIUS: I would -- again, I would argue and answer to these issues differently depending on whether I'm arguing for an interim mandatory or for something that's going to go under HACCP. If you're looking for an answer that applies to both, which I think is what you're -- what you said, and correct me if I'm wrong, I would then defer to what Bruce had said and the agency's own study on cooling, they used E. Coli 015787, but what they didn't use -- didn't take into account entire growth curve of that particular organism. They only looked at the multiplication stage. If you take into account the entire -- the lag phase, the multiplication, and static growth -- you know -- you get a better picture of what your capabilities are and where your health significant or food safety risk lies. Your answer might be right there.

MR. TAYLOR: Right. And that's very germane scientifically, obviously, to devising whatever the appropriate standard is. But let's -- just so we can frame -- give you a framework for giving us your input, let's focus on HACCP. Let's say that we're talking about HACCP being implemented. We're in the HACCP mode. What should be our approach to evaluating whether our plants are meeting its cooling -- its chilling responsibility under -- under HACCP?

MR. POCIUS: Under HACCP I would look at cooling as one amongst many steps in the process. And if you are looking at targets,

which you did say you were going to do, then that is one hurdle amongst several and it's additive, it's energistic, we don't know, but the end result is that these things go together to reach the desired result.

MR. NEESE: Sir, I'm out of order but I want to say I think we're missing the point. As a generalist I've been taught the entire time I was in the meat industry that the internal muscle of an animal is basically sterile until you expose it to the air. So what difference does it make if you're twenty four hours or thirty hours? If the muscle is sterile the bacteria's not going to grow. No bacteria.

MR. BILLY: Dane?

MR. BERNARD: Thank you. Dane Bernard, National Food Processors Association. First of all, I'd like to thank Bob Garfield from AFFI for setting up this room today, the American Frozen Food Institute, certainly made it cold and logs so those things were going to have to burn on this end of the room just to get through the next couple of days if they don't adjust the temperature.

Having listened to the discussion I'd like to go back to the first point that was made. We haven't disagreed at all if you listened to the tone that refrigeration chilling is important. Everybody here said it -- it is. The argument has centered around how do we measure compliance, if you will. Do we set a number? I think the vast majority of comments we've heard has said we don't know what that number means in terms of science. And if we think about what we intend to do with HACCP, which was your last point, how does this put this into a HACCP system? And let me relate to having worked through many beef slaughter HACCP models with companies. We always come to the point where we've developed a model plan and just to throw some numbers into it we'll say we're going to chill the carcass to a surface temperature of fifty degrees within ten hours. Then we ask the question, what happens if it's fifty one? What does that mean in terms of the safety of that product? If we have critical limits in HACCP plans, as we said at our meetings last week, that don't make sense in terms of science then plant management as well the inspectors in the fields and those who must deal with those plans are going to call the whole process into question. We have not at all said that refrigeration and cooling is an important. Absolutely it is and we've even heard that it's a critical control point in many HACCP plants. So the whole discussion is centered around what's the appropriate number. And as Bruce Tompkin laid out very well as a real microbiologist, not a pseudo

microbiologist as I am, that it's really a triad that goes into determining whether that product is safe. It's the initial contamination level. If we didn't have the pathogens here in the first place it doesn't matter how bad we kick it around it's still going to be safe to consume. The other two elements of the triad are the actual temperature itself and the time of exposure to that temperature and because the dynamic of those three in the actual field, we don't have good data to come up with a specific cooling guideline that's going to fit every operation which brings up back to HACCP and determining within your own operation, and probably reluctantly because everybody knows my position on microbiological testing. We look down here on billet 3 and some microbiological target as being probably the measure of whether we have an adequate system to control the cooling rates of the carcasses of animals that we're talking about. So it's really coming up with a performance criteria that leads us to numbers that feel good.

Once again I'd like to harken back to what we were doing five years ago in terms of HACCP overall. We sat around tables arguing about whether HACCP should wrap around quality and economic factors instead of going out and teaching, adapting, and implementing and I fear that because we all agree that cooling is important that arguing about exactly what a number is is creating another similar roadblock to just going out and making things better because we know it's important even though we don't have a hard number. We look at performance criteria. Thank you.

MR. BILLY: I got Eric and then Dell. Then we'll have a break and warm up.

MR. JUEGNES: Eric Juegnes, American Public Health Association. I think when it comes to performance standards it's important to remember that there is a public health function that is served by them. First of all, as Assistant Secretary Taylor mentioned, they serve a very vital role as far as providing accountability and evaluation. Right now from what I've heard going around the table there's certainly scientific uncertainty about exactly what that level should be. However, I don't think that mitigates the usefulness of that minimum standard. I think, first of all, it provides some measure of public confidence and in the public health departments an ability to assess what's going on in these plants and it also serves the purpose that the standard is to protect the entire population of consumers from

the entire population of producers that may produce a contaminated product. From that standpoint, whereas at this table many people may be meeting the cooling requirements, they may be producing safe products, that doesn't mean that having a minimum standard that will apply to a wide range of producers is not going to protect the public better and I haven't heard any definitive negative science that says there is nothing to be gained by this. It may be that the minimum standard needs to be set and then as more data comes in it can be modified. It may be that we need to look at allowing some plants to opt out so long as the public health basis is not opt out if their HACCP plan is already meeting the requirements so that we don't have a situation where marginal violations of the temperature's going to shut down the plant if public health is not compromised but I don't think that we can just wholesale say we just should leave the whole issue up to industry flexibility because I'm not so sure that that will best serve the public health. Thank you.

MR. BILLY: Dell?

MR. ALLEN: Dell Allen with Excell. I think all of us should take into account, first of all, we don't need -- and I call on the camp of several people -- we don't need regulatory action where maybe regulatory action is not needed. I think that should be the goal of all of us not to put some type of an arbitrary regulatory thing into practice when it really doesn't have a practical purpose. Maybe we should all take comfort in the fact in knowing that there are a lot of economic drivers beyond food safety, not an exclusion of, but beyond food safety that dictate that we rapidly chill carcasses as fast as we can.

Your sister agency, the AMS, who have representatives in all our fed beef plants, are a guardian of adequate cooling of beef carcasses. For a full weekend grade a beef carcass that agency requires it be adequate chilled as they assess that evaluation before they'll grade it. And we have got to meet those guidelines in other words to get our carcasses graded in our coolers. Now, what are those guidelines? They don't have a number on them. But it is a visual evaluation of that rib eye and they're very good at it, and it equates into the fact that rib eye temperatures typically have to be somewhere in the neighborhood of thirty six to forty degrees fahrenheit before that carcass is ready and presented to the grader. We have to chill them to that point before we bring them by there. Now, if you're operating at twenty four hour chill plant that's basically what your guidelines are. If you're

operating a forty eight hour chill plant you're still going to be at those temperatures before you go to present them to that grader. In addition to that, we have customers, and I think everybody's under this gun, will not accept trim, for example, shipped to them over forty degrees fahrenheit. So we've got to get that product to that temperature before it goes out the door. Our ground beef customers are demanding it even to the extent of being below thirty five anymore. So there is another important thing to keep in mind quality-wise. If we don't chill carcasses temperature-wise as fairly rapidly as we can we have a deterioration in muscle quality which shows up in problems to us from a consumer standpoint. In the pork industry, it shows up as PSE pork -- a higher incidence of it. It's in our inherent best interests quality-wise to make sure we chill as rapidly as possible. And so there are a lot of economic things that drive us to chill properly beyond just food safety. I think food safety is inherent and is probably the most important part of it. But there are a lot of others that are dictating to us. Because of that, I have great difficulty sitting here thinking that we need to establish some arbitrary temperature that everybody's got to meet when in fact we've got so many different situations that it makes it extremely difficult for one size fits all requirement. I'd just add to that that in the fed beef plants is where we have the most difficulty to getting beef carcass temperatures down because of the size of the animal, the fatness of the carcass, etc. On our cow plants where you would not get into grading they are thinner fleshed animals, they chill more rapidly, they chill more easily, we don't have those same problems in those types of plants. And so it's a problem maybe we're worrying about way beyond the criticalness of it.

MR. BILLY: Caroline, is it right to this point or you want to --

MS. DEWAAL: Right to this point.

MR. BILLY: Okay. I'm going to hold that and I'd like to take a break for twenty minutes. Be back at quarter after eleven.

(A brief recess was taken)

MR. BILLY: Okay. We need to get started. A couple of announcements. One, we have followed up with building maintenance and while we make no promises we're hopeful. Secondly, the court reporter's asked me to remind everyone to state their name before they speak so that he can keep track of who is speaking.

I'd like to break about twelve thirty and we've got roughly an hour remaining. I'd like to -- you know -- have a little more discussion on

this. Two or three people have asked me to be recognized. I was also struck by -- we've heard from one of the people representing a small plant but we haven't heard much from others so maybe we can hear a little bit more. There was a set of comments, in particular, from that perspective but I think that it's important to add to this discussion.

So, Caroline, when we left off you wanted to say something?

MS. DEWAAL: Thanks. I'm actually -- I wanted to explore some issues raised by Bruce Tompkin and also Dane. I'm struck by this concept that we don't have the right numbers for pathogen control. And somehow -- you know -- this isn't -- we can't really do anything in this area because the numbers don't exist. I mean the numbers -- correct me if I'm wrong but, Dr. Tompkin, you gave us numbers for control, both E. Coli and salmonella and they were in the range of forty one to forty five degrees. And the -- also there are references which we cited in our comments on coliform E. Coli and L-30 and salmonella and the range was about forty five degrees to fifty degrees fahrenheit-- 7.5 to 10 degrees celsius. I guess my question is, don't we have numbers that tell us about pathogen growth that then we can work off of to determine what are appropriate control numbers? That's my first question. And the second issue is -- goes to the issue of how to apply. If we do have those number, how to then apply them and -- you know -- is the agency's approach, which is to look not at -- they're not dictating controls for the plant overall but they're dictating a control for the product so it's product specific. I mean what the issues around applying that standard to cooler temperatures, to temperature on the processing floors, which is both issues, deal with some worker safety issues and then also for temperatures during transportation. I have a particular concern that you not transport product if you're cooling a product down using a long term method so you would achieve the cooling temperature within ten or twenty four hours or whatever it is that you do not then transport the product while that cooling's going on because you're going to stop the cooling process. And I'd be interested in your views on that.

DR. TOMPKIN: Well, these lower temperature limits, the rates of microbial growth have been used in developing the recommendation from the agency. They're based on growth rates under optimal conditions in broth medium and that gives you some helpful information. It perhaps may be worst case. The question is, what is the real rate of growth on a carcass? So the attempt was made to

transfer information from broth cultured data to carcass surface data. And that's a difficult thing to do and for that reason it's better to actually do tests on carcasses to see whether in fact multiplication occurs and that's what's been done in Australia to determine whether, in fact, there was increase under their particular conditions and that's where microbial tests at a plant level could be used, whether it's for E. Coli, just generic E. Coli let's say, to assess whether, in fact, microbial growth does occur during the cooling cycle. That information could be generated under a specific plant's conditions and then they could reach the conclusion, yes, we do or do not have, say, a one log increase and that was one of the options that was proposed. And then that essentially would validate that that specific critical control point is under control. You wouldn't need to do that microbiological test on a daily basis. You essentially know that under these conditions of operation -- air flow, temperature, spacing, loading, how many carcasses per space, and so on -- knowing that information under which the data were generated then you have other ways of controlling other so-called critical limits, for example.

MS. DEWAAL: Did they apply that to all their plants?

DR. TOMPKIN: I don't think that this has been done across all plants that I know of. I'm speaking as a microbiologist when I spoke this morning. I'm not in the beef industry anymore. I used to be. But I think -- I don't recall that there's been that much data in the U.S. done actually on microbial growth during the chilling cycle and published. You may find that in commercial facilities where they have, in fact, done that themselves. What you're suggesting or whatever the direction we're going is that the individual plant, or it could be a group of plants in the case of smaller processors, or some other organizations, they'd have to get together and come up with an agreed upon set of conditions under which they could operate and run a test to validate it and say, okay, we can live with this and it does meet the public health goal. That kind of thing could be done.

MR. BILLY: Jim, on this point?

MR. LOCHNER: Jim Lochner, IBP. I do have some unpublished data on two different hot box chillers that have two markedly different cooling rates and I utilized infra red thermography to assess the rates. What you'll find -- in the one called a fast chilling cooler did come close to what was prescribed but not quite. So a fifty degree in five hours, I think, we had an average surface temperature of over

forty degrees in five hours but still roughly about ten percent of the surface area of the thick muscles over fifty degrees. And then the other cooler was sixty five degrees average with 99.5 percent of the surface area over fifty degrees. We looked at a number of carcasses at zero hour entering the hot box, five hours after being in the hot box, and twenty four hours after the chilling cycle's complete. We looked at a total aerobic plate count E. Coli species and tried to -- and salmonella -- which we found no E. Coli species or salmonella on any of the sample times or carcasses. But the aerobic plate counts actually had a log reduction between zero time and twenty four hour of 1.1 and .8 for the shoulder, clod, and round, respectively, for the slow cooling and .8 and .55 for the clod and inside round on the fast cooling which a log reduction -- when I come back to your point of established cooling performance standards expressed in the maximum acceptable pathogen a total aerobic plate count is not pathogen but what we probably aren't going to see basis -- what Bruce Tompkin has said -- we're not going to see log increases.

Back on the other point. I wanted to -- the point I wanted to make earlier on chill rate -- I think everybody, and I think it's been expressed, agrees -- the frustration of what was proposed and I'm going to ask the agency this question. Was it researched from both an engineering capability standpoint and reality standpoint and food safety and quality? Because it all comes into play. I don't believe the physical engineering was done prior to the proposal and that's the thing that was most disheartening, I guess. We came out with a proposed regulation for carcass surface chilling and something, for all practical purposes, was very difficult to nearly impossible to achieve on a hundred percent of the carcass. Thus, it was destined to have a fair amount of problems. And I think the other point I wanted to make earlier as well is nobody's arguing the necessity for temperature control, particularly it's very critical on trimmings and ground beef which has been expressed earlier. And it is critical on sub primals but not at forty degree fahrenheit. And I think we have to go back on all these issues and adequately resolve them with engineering capability put into the equation.

And the last point I want to make is we've talked heavily about pathogen and chilling rate in beef. For years you've had temperature regulation in poultry, yet, in very stringent ones. Yet, the pathogen percentage is considerably higher. I think before we leave the

temperature area we need to discuss why that might be.

MR. BILLY: Okay. Dane?

MR. BERNARD: Thank you. Dane Bernard, National Food Processors Association. I'd also like to hear the answer to some of Jim's questions when you get around to that, but in the spirit of dialogue, which is what we're supposed to be about here, let me comment further on some of Caroline's questions and also go back to something that APHA said a bit earlier -- Eric.

I can't agree more with what Bruce said in terms of laboratory studies and then taking those laboratory studies and turning them into a hard number. That's where we have problems. In fact, if the numbers don't make sense, and this gets to what Eric said earlier in terms of is there a problem with knowing something of this nature and he hasn't heard there's a down side to it, I think the real down side is that when we mandate the things that don't make sense in terms of science, in terms of having it rock solid, and it goes against convention in the industry and we know there are problems with implementation in certain segments of the industry, we're going to run into these kinds of discussions, and, again, what I said earlier about we know there are some things that need to be policed up in certain quarters of the industry on temperature control and we ought to get out and do that. Arguing about the number itself is not getting us to the point of saying, okay, let's go and take a look at temperature control and do what needs to be done to make it better where it needs to be better. If you look at, by the way, engineering studies on the bumble bee, the damn thing's not supposed to fly but anybody who's walked into one of those nests knows that it does fly. It gets us back to the fact that we can do our best in the laboratory and come up with things that work in the lab and optimal conditions but we know based on the data that people like Jim Lochner have presented that the things that have gone on in Australia and New Zealand that the numbers just simply don't reflect a clean situation that's specifying a temperature per se is not necessarily going to us what we want out of this whole situation. So while there is scientific data, even the USDA's model says that in a dynamic situation the minimal numbers that we come up with in terms of temperature of growth in the laboratory really don't give us a full picture when we take those to the field. Thank you.

MR. BILLY: Ed?

DR. MANNING: Ed Manning, National Association of Federal

Veterinarians. It's very interesting to sit around -- sitting around and listening to all of the various agenda and turf protections, etc. going on and most of them with a lot of good foundation as a matter of fact. One thing I'd like to mention is I keeping hearing -- you know -- if the system isn't broken why try to fix it. And we don't believe that the system overall is broken. However, we do feel that a computer virus or something has been inserted so that there is some significant fine tuning needed, be that with E. Coli 0157 or whatever. Also, speaking specifically of temperatures, a system can't be broken if it doesn't exist. And for red meat there is no temperature control statement. So nothing can be broken or not broken with that. Various other parameters that have to be looked at, even though some may be less significant than others, but the lag phase will say for E. Coli at fifty degrees being two days is true. However, we must remember when a beef carcass first enters its chilling environment, whatever that may be, that carcass is far from fifty degrees so the organism has not entered any lag phase slowly for the fifty degree mark but it's there for seventy, eighty, whatever it happens to be.

Next, organisms of a hundred organisms per square centimeter are something. Insignificant in many areas. However, that is sufficient to cause severe illness with 015787, so even with no growth, let alone a little bit further. Next, temperature of beef carcasses being checked by AMS and the graders. This is very true. However, we must remember that the highest risk to beef is not that which is being graded, therefore has no temperature check by anyone. There is obviously great variability needed and a flat temperature across the board for all products is not going to work. There should be an exception written in so that as the gentleman from Carolina mentioned with the pork, with a superb procedure like they seem to have, if they're chilling it down very rapidly but not to the point where it would be allowed to be shipped to another plant twenty miles away or something, that refrigerated shipping should be part of the whole process and should be allowed. So one has to look at things such as that as well.

Next on now versus HACCP. If temperature controls go in now what will happen with HACCP? Again, as Marcia Clark and Chris Darden last night in summing up O.J.'s kept saying, use common sense, let's use common sense, hopefully common sense would prevail and obviously if temperatures were mandated now HACCP program that is

set up and working would include the temperatures necessary for it to work for that critical control point. Contrary to a statement earlier, critical control points are going to have to have standards of some kind, be that temperature or microbiological or whatever, or you don't have a measure of whether that critical control point is working. So standards will have to be there or you don't have critical control points in HACCP. And then, finally, I think it comes across strongly to me that the outstanding plants represented by the people here today really are not looking at reality but only their situations which probably none of them need a specific temperature control of things but we don't need a criminal law for theft if no one stole and there is, as I think Mike Taylor mentioned earlier, a percentage, whatever that is, that the regulatory system is responsible for who do not wish to abide at many points that they can get around abiding for and they will continue to do that and everyone appears to be agreed the time temperature relationships is the critical control for bacterial growth. So all we have to do is, with common sense, hopefully, come up with the attainable biotechnology, minimal possible temperature that science can justify, and flexible for various modern technology that would allow little deviations within a time period but overall still attaining that reduced criteria. And, hopefully, we will come to that. But remember, there are people out there right now and they will remain unless you all can drive them out of business who are going to cut corners.

MR. HANKES: Can I interrupt here real quick? I guess -- Jim Hankes with Illinois Meat Processors Association. One thing, Doctor, I think you brought up that disturbs me and I think was brought up a little earlier was that there are a lot of good small plants out there. It's just that for a small operator to get down here to Washington, D.C. and to be away from their operation for four days is pretty darn difficult and so obviously they're relying on several of us from our state associations and national associations to help represent them and we do know that there are other plants out there that need help. They probably need -- you know -- stronger regulations but I guess I would like to say that not all the good operators are here. There's other large and small companies that are good operators that are not here.

DR. MANNING: I would just say I was not trying to insinuate that the only good companies are here but that those here are good

companies. Okay.

MR. LEIDY: My name is Terry Leidy. I'm from a fourth generation family business and one of the reasons I am here today is because my brother and the rest of the family can run the plant when I'm not there.

I'm very concerned about temperature being cut in stone of say forty degrees. My question would be, on whose thermometer? For instance, who calibrates that thermometer? Who reads it? And if it is forty two degrees what do you do with the product? That doesn't necessarily mean it should be rendered or deemed inedible. I don't think that's been addressed and I think it's a key issue that will have to be addressed. The engineering and service and science question a while ago I'd like to know too if the agency really has studied those two aspects. The transportation of the product I think's a key also after you've met the proposed requirements. Most of our product is shipped all over the country. What happens if the common carrier has a problem? Who's going to be responsible for those problems? If it comes back to the federal plant I understand we'll have to have some sort of a method of handling that product. But on the small side, which I'm part of, to lose the product would be a tremendous loss of possibly good product, but, again, what are we going to do with it?

I appreciate being here. I think it is a good idea. There's a lot of people from family, medium sized, and small companies that aren't here and I think it's a key part of our economy that we should think about those people. Thank you.

MR. TAYLOR: It's Mike Taylor. I just -- the transportation issue is one we talked about a week before last in terms of the farm to table strategy and you're quite right, we don't currently have any standards or oversight for transportation and that is an issue that needs to be addressed. We are currently working with FDA and we have had a technical advisory group working to give us some input on how to address that. I mean clearly it's part of the picture and very important.

MR. BILLY: Rosemary?

MS. MUECKLOW: Yes. This is Rosemary Muecklow, National Meat Association. Kim keeps reminding me who I am and I appreciate it.

Mike, you gave the impression in some comments before we broke that the state of the art people were here and it's too bad all the rest of them didn't come. I glad they didn't because we'd have to be darn

freezing in the Washington Convention Center or the Jefferson Auditorium. I don't think you probably intended to give that view. I would remind you that your notice of August 31st asked that interested parties with common concerns and positions on a particular issue are encouraged to designate a representative to speak for them on that issue and, indeed, there are some of us around the table, several of us who tried to make sure that we come to the table with group views because you really didn't want to meet all of those people. The people who are here are outstanding companies. There are many outstanding companies out in the suburbs who are working diligently trying to produce safe meat today and I wouldn't want it to be in the record that you thought that they were less than the best because many, many of them are outstanding firms. It is true that you have to draw a line and you have to take regulatory action against people that will not or cannot meet the requirements of the law. And this industry, including the organization that I represent, understand that and we work very cooperatively with the agency to make those people meet those requirements. And so, you have got a lot of legitimate representation here. We know there's always the possibility under any system in our nation where we're going to get a few bad eggs out there but since Dr. Manning echoed the views that you had I just wanted to give you a chance maybe to straighten the record on that.

The other issue that I would like to raise is that sitting on my left hand side is Dr. Ranzell Nickleson from the Meat Board and he has pulled together and worked with this industry for many years and he made a very telling point to me on a piece of paper and I'd like him to bring it to the entire group because I think it's very germane to the discussion of the cooling issue and the points raised around this table and should we even be here talking about cooling issues. Is that the critical control point? So I would like to ask Dr. Nickleson if he could follow up on that.

DR. NICKLESON: Thank you, Rosemary. Nick Nickleson with the Meat Board and Siliker Laboratories. I guess I raised the same question Bruce Tompkin did. Do we know that carcass cooling or non-cooling is a problem and a safety issue from the standpoint of pathogens? I don't think it necessarily is. The reason being is we have pretty good process in progress right now. It is a preventative process. We have low incidence levels and low levels of pathogens as reported by the National Baseline Survey. Even if refrigeration is not adequate,

dehydration on the outer surface of a carcass, any relative humidities below ninety five percent, we're going to put most organisms into a prolonged lag phase which brings up the model, again, that Bruce alluded to. If you try to plug some of these pathogens into the model the model does not go low enough, not into these temperatures we're discussing as potentials for regulation. Is cooling really a critical control point? That's been mentioned by several people today that cooling is a critical control point. If you follow the decision tree and you follow the concept of HACCP only dealing with safety issues I'm not sure that cooling itself is a critical control point. It is a control point, it's part of the GMP's, it's going to extend the shelf life, marketability, and economics of a product. There are buyer specifications that are also directing the presence and absence of pathogens in proper good manufacturing practices. If cooling is not a critical control point then maybe I confused the issue even more by suggesting that non temperature abuse, non temperature control or temperature abuse is the critical control point and that deals all the way from carcasses through to consumers thawing product on the counter. Thawing product on the counter's fine as long as it never reached a certain temperature on the outer surface. With the temperature abuse potential that's there is what is the safety hazard and so I think if you put this broad umbrella of what is temperature abuse it's difficult to place a specific temperature will apply to all commodities and all processes. Thank you very much.

MR. TAYLOR: This is Mike Taylor. Let me just, as Rosemary invited me to do, make sure the record is very clear that certainly there are thousands of very responsible committed plants doing a good job on carcass cooling and only a small sub-set of those are in the room today. I mean that -- I mean obviously that's the case. Again, we're looking for some -- you know -- the question we're trying to ask ourselves is -- I mean given the recognition of the importance of cooling and of food production system in a carcass in a slaughter operation what is the practical means of insuring that plants -- and, again, our focus is not the thousands that are working hard and at the state of the art -- what's the practical means of having some accountability for those who are not there, whether because of capacity or commitment, or whatever it might be? Is there some minimum standard, some measure of accountability for those? That's the question we're grappling with. So, again, the -- let me just say --

briefly respond to a question that was raised earlier about the proposal and -- you know -- the preamble to the proposal and the rule itself tried to make clear the intent and -- you know -- which was not to -- the intent was not to alter the state of the art in the well run establishments. The preamble's explicit that the proposal was the agency's best estimate, if you will -- that was the term used -- of what's achievable in the well run plant. The proposal also included as an alternative to the time temperature requirements that we've been discussing and is the object of so much of the comments -- the five hours to fifty and so forth -- the proposed regulation provided an alternative whereby plants could devise alternative time and temperature parameters based on there would be microbiologically equivalent was the term used in the proposed regulation. What the comments have told us is that the specifics that we proposed may not be what's achievable in the state of the art plant, number one, and, furthermore, don't take account of the wide diversity of plants and production processes and so forth and so, again, you asked what was behind the proposal. That was it. The comment process -- I mean what we've gone through with the written comment process and going through today is what proposals are all about. It's an attempt to lay out some objectives, lay out the agency's best thinking at the time of the proposal and then to stimulate the input which, again, the written comments provided us were in very substantive detail. And, again -- you know -- we're -- I think the paper today was intended to make clear that we -- you know -- we've heard and we've recognized that there's a diversity concern that our proposal doesn't take account of, there's a technological issue about the specifics of what we've proposed, and that we've got to -- you know -- fundamentally rethink how we achieve the objective that I've, again, mentioned this morning which is some practical means of accountability for plants, particularly those who are not currently meeting what might be thought of as current good manufacturing practices. How do we have some means of holding those plants accountable? That's the basic question.

MR. BILLY: Eric?

MR. JUEGNES: Eric Juegnes, American Public Health Association. I just wanted to respond to Dane's comments. I think he's absolutely correct that standards that accomplish nothing undermine public health efforts, credibility, and so forth. Fortunately, I don't

think that's the case here. Just from this table, there's obviously temperature ranges that we can identify for growth. The nature of risk -- the risk assessment process is such that a lot of public health decisions are made in the gray area between wholly negative and wholly positive findings. That's life. That just necessitates that you have to make the best estimate and the best decision possible. Minimum standards -- the basic fact is help protect vulnerable populations by augmenting, I guess. There's two types of accountability. One type is economic accountability and that's if somebody's producing a bad product, consumer groups raise a ruckus and they're going to suffer economically. However, there are sub-sets of the population that are both vulnerable and particular to the hazards of contaminated products and also lack the consumer power because they can't get organized. These minimum standards help provide accountability allowing for enforcement actions in monitoring that helps serve these vulnerable populations and, in fact, that is one of the motivating factors behind proposing these regulatory changes in the first place.

And I just wanted to respond to the fact that poultry has chilling requirements but yet they still have high contamination levels. It's actually my understanding the chilling requirements were required because of those high contamination levels and that there's certainly differences in the processes that are allowed for poultry that are different from beef that I don't know that make that a very helpful comparison. Thank you.

MR. BILLY: Gary?

MR. CRANE: My name's Gary Crane. I'm a past president of the Oklahoma Texas Meat Processors and I'm currently serving in the office as president of the American Association of Meat Processors. I'm located in a small rural community in north central Oklahoma called Perkins. We run a small plant. We've been there in business for thirty six years. I employ approximately thirty five people. Me being a member of different things, over the years being there for thirty six years, we did a lot of remodeling over the years, so I feel like even though we are a small plant we have kind of kept up with some modern standards. All of our cooling capabilities, I feel like they're not what you would call state of the art like some of the big processors but for a small processor I really feel like our plant is a state of the art plant. But anything that we do do, and I know a lot of other processors do

over the country, is a lot of your bulls are slaughtered in these small meat processing plants. And there's big processors out there also. I guess it's like any other form of food product that we make. But if we go setting these time and temperature frameworks or standards, anything that really came to my mind last night and I thought about it here this morning hearing this discussion, approximately three weeks ago we killed a bull. This bull dressed out 1,761 pounds. That was his carcass weight. He was an ideal bull. If I could get five bulls like this a week I could slaughter five bulls a week instead of ten that I have to slaughter now. But when I say he was an ideal bull what I'm -- the point I'm wanting to make is that he was such a muscular animal, fantastic animal, that our chill room we run at twenty eight degrees with considerable air velocity in there. We place our animals in there from all during our day's kill and the next morning we move them into our holding cooler. Our holding cooler is thirty six degrees. And our holding cooler's also where we -- -- our bulls. The next morning we were behind on bull meat and we did get this bull down first thing and start bulling him out. We did not measure the temperature. The beef inside the rounds or inside the shoulder clod, which I wish that we would have done at the time, but whenever we opened up the animal so you could see the moisture vapor -- you know -- coming off of the meat and the whole -- I'm wanting to say is that when they set standards for given different species, whether it's poultry or pork or beef, in some of these, even within the species there might have to be different time limits, different temperature ranges there because just the size of the animals. Say, in hogs, like Terry does down here. I know we -- you know -- he slaughters a lot of market weight hogs and then you have your sow processors. Those are big heavy sows. And the carcasses just aren't the only chill at the same temperature loss even in the same cooler but it's real important to me that we do consider the different sizes of animals and within the same species. Thank you.

MR. BILLY: Richard?

MR. MAY: I find it difficult to sit here and what you're apparently beginning to say is you're more guilty than I am and if I could defer to poultry or chicken that being dirtier than other animals. I think we need to remember how our historical tests have been taken, where we've tested a beef carcass with a twenty five gram sample which we cut a perfect cube out. Only one-sixth of that would have an contaminant on it. And we test a whole three and a quarter -- three

and a half pound chicken which has about two thousand square centimeters on it. If we find one pathogen we say it's positive. So I don't want to degenerate into saying you're more guilty than I or anything else. I think we're here trying to discuss how to make a better system. We in the poultry industry do our best as does everybody else and I think it's very clear today that larger animals are more difficult to cool and it doesn't necessarily mean that you're creating a hazard with them. They just take longer to cool. They're a -- -- profile and you can't cool the inside of the carcass nearly as quickly as you can with a smaller carcass like a bird that we process. And we use a moist medium to chill our's which is faster than an air chill. But I just wanted to make that point. We think we have excellent products compared with anyone.

MR. BILLY: Richard?

MR. BECKWITH: I'm Richard Beckwith with Hill Top Pork in Canton, New York. I'm probably about the smallest processor here. But I just want to coattail on what that gentleman said down there and what Mr. Neese said up here. I think what we're talking about here is an issue of flexibility; a flexibility with different situations. Our particular situation is we basically slaughter that day, it goes right directly into the stores the following morning. I guess what the biggest fear is, the biggest fear from small business, and I'm talking small business in general, is to be manacled by a certain approach. I guess we would have to see if -- see, because the whole concept of small business is the flexibility. Your small businesses are located close to your marketplaces and so on. Our selling point is we can get the product to the customer faster versus, in all deference to our friends from the Midwest and so on, I can have product to a particular store in one day versus five. So I guess the bottom line criteria isn't so much a temperature thing. I think it's a shelf life and bacteria count. So that product might come in at fifty degrees and be sold that same morning versus a product that was shipped three or four days earlier form the Midwest, is the bacteria count on that product higher or lower or whatever. I think it's not so much the cooling parameters that have to be resolved. I think the bottom line is -- you know -- what the actual bacteria level is.

MR. BILLY: Joe?

MR. POCIUS: Thank you. I want to -- actually this probably ducktails well with what was just said. I want to go back and in

response to what Ed Manning had mentioned earlier. Actually, we agree with him that cooling will be strictly addressed within the HACCP plan. He called it common sense and he said that standards would be included in the HACCP plan. In the HACCP plan they'll be called critical limits and it will be specific for that HACCP plan so we're talking words mincing here. But I think what needs to be clearly stated here and during the break I talked with some people and I think there was a misunderstanding of how these things would be handled and I'm strictly talking about HACCP now because I didn't get a clear answer as to whether an interim was interim or not. But within the HACCP when these cooling parameters, if it's made critical control point, and for our industry, we did determine it a critical control point, it will be described, it will be written down, it will have critical limits. It will have corrective actions. Moreover, the industry takes on a much greater responsibility in putting it in its HACCP plan than just having a cooling program because if it's critical control point and if it fails that line is subject to stopping and that product is subject to detention and the whole HACCP plan is subject to review. So it becomes much more important. This isn't a giveaway. We're not asking to put it in HACCP because we want flexibility and we want a giveaway. We pay for that flexibility. If we fail what we say we're going to do it has a much greater impact on our businesses. That needs to be understood up front.

The other thing that was mentioned about lag times and product coming in, it's not at fifty degrees and so we should be careful about lag times. I agree. But referring to the agency's own cooling study and, again, they used 0157 as their reference, product at a hundred degrees fahrenheit now -- all these are in fahrenheit -- has a lag time of an hour and a half. Well, isn't very much product that I know of that once it's slaughtered stays around hot that long. Certainly, in the turkey industry that product is temperature reduced very quickly. I goes down to sixty degrees in a very rapid, very short period of time. In that study, at seventy degrees, the lag time increases to six hours and so on. Once it's down to the fifty degree area you have 50.9 hours of lag time. This is even before we start talking about a log phase -- a growth phase. So you have to keep that in mind too that we don't jump the gun and look directly at the log phase without keeping in consideration what we need to go through to get to that growth phase.

MR. BILLY: Jim?

MR. HODGES: I'd like to try to refocus the discussion a little bit of why AMI recommended that the time temperature requirements, for that matter all the other near term requirements, fit into the HACCP program. I think most of the people around the table can see that cooling is a CCP. I'm not sure that's unanimous, obviously, from the previous comments, but clearly that CCP would entail monitoring of refrigeration equipment, chillers, environmental temperatures, and a variety of other kinds of things because without those there is clearly -- if there's something that goes wrong in those processes clearly you could have a food safety hazard. If we can see that cooling is a CCP the question I have is why is the Department going to treat that CCP different than any other CCP in their HACCP program. It is my assumption that the Department will validate those -- the companies will validate and the Department will verify that those programs are adequate and they are being operated properly and it just seems counter-productive to set some arbitrary performance standards outside of the context of the HACCP program. I think it just begs the question of are we headed in the right direction philosophically which -- you know -- I agreed -- you know -- Mr. Taylor, with all your comments generally, I think philosophically we're headed in the wrong direction by mandating time temperature requirements.

MR. TAYLOR: I understand that to be your position and as you can see by reading the paper today, I mean were we considering that concept to mandating time and temperature and that's what the options are about and I appreciate your comment.

MR. BILLY: Caroline?

MS. DEWAAL: I just have two quick points. First of all, I really have to respond to this issue of defrosting the roast on the counter. I know that if a consumer defrosts a roast on their counter and if they do it properly they're probably not putting their family at risk and yet from a consumer education standpoint we have to tell them not to do that and in also when we look at cooking temperatures I often add about five degrees to what I know is an appropriate cooking temperature because I need to incorporate a margin of error into my education message and one of the issues I think the Department needs to deal with and I think you did deal with it in the initial proposal, but when we always talk about basing things on the science, are we addressing the issue of margins of error? And are the companies -- I mean are we asking enough of the company to ask them just to meet

the scientific standard or not to meet it? I think we have every right to expect as much of the industry as we expect of consumers and I think it is appropriate to build some margins of error into the proposal. I think the original proposal which put the cooling temperature at forty degrees did that. And I would ask the Department not to throw out that concept as you're looking at new proposals.

The second issue, I just want to raise, is in looking at this issue of cooling methodology, and, again, this moves into option one versus option two here, in the poultry area there is clearly evidence that the cooling methodologies which may accomplish cooling in a very short period of time also spread contamination. And at some point the Department has to address the issue of -- it's fine to achieve the cooling objective but when you're also -- when you're also resulting in a far more contaminated product at the end of that process are you really achieving your objective? And perhaps option two addresses that somewhat more than option one does.

MR. MAY: This is Ken May of the National Broiler Council and there is ample scientific evidence, more than one paper, Caroline, which we would be delighted to furnish you, that shows that chilling with chlorination in the water we do not get cross-contamination. And I know there's been all sorts of names applied to liquid chilling. They're just simply not true. The scientific evidence is there. We do not cross-contaminate when we properly chlorinate our chillers which our entire industry does as a matter of good manufacturing procedures.

MS. DEWAAL: Well, I have a list of studies that seem to indicate different results and perhaps you can provide -- I mean it's not us but --

MR. MAY: We'd be glad to -- USDA has done it -- two different USDA studies have demonstrated that chlorination takes care of that problem and it's not industry studies. They are done by USDA.

UNIDENTIFIED VOICE: Is chlorination mandated?

MR. MAY: Chlorination is not mandated but it's a part of good manufacturing procedures that the National Broiler Council has published that all of our members follow.

MR. BILLY: Carol?

MS. FOREMAN: Carol Tucker Foreman. I think I need a point of clarification. On the interim requirements, if a plant has a detailed HACCP system in effect will it be required to comply with the interim standards for carcass chilling?

MR. TAYLOR: This is Mike Taylor. What the proposal said in effect was that if you have your own time and temperature provisions that are microbiologically equivalent and those are reflected in your plan then you don't have to comply with the specific time and temperature proposal -- you know -- elements that we've been discussing.

MS. FOREMAN: I wasn't sure that had been brought out this morning. I did think that that flexibility is there so you wouldn't have to change an existing HACCP plan to comply with this.

I'm kind of inclined as an individual toward the option three because it goes to the performance standard on the item that we seem to be concerned about. Let's reduce the things that make people sick and it seems to me that's the ultimate standard here if plants can show that their HACCP plan keeps that under control on a regular basis I'd be inclined to be comfortable with it.

I know we're going to talk about the small business issues tomorrow. I've been intrigued by the variety of problems have been raised here today. I think it's been a wonderfully educational process. I happen to own a business. It's a small business. I still have to fill out all the same forms and provide my employees with all of the benefits that are required by the State and some additional ones. I have to go negotiate for health insurance. Big companies get to -- a far different situation in buying health insurance than we do. We have no market power at all. There are certain handicaps to being a small business. If you choose to be one you live with those and you try to price your product at a level that lets you compete effectively and you compete in part by having the flexibility that the bigger company doesn't have. I'm probably going to repeat these same points tomorrow. There are some obligations to being in business and I think that it's imperative that within this flexibility I want to see something that says you show that you're effective in preventing the things that keep people from -- that make people sick. If you're effective in preventing it then you get to have the flexibility of doing it the way you would like to do it. I think that's what small business most often needs. I assume that's what large businesses need. I've never been a large business.

One final point. I thought it was very interesting the comment about pathogen -- about bacteria growing at fifty degrees and I thought perhaps the temperature in here this morning was designed to prevent

that.

MR. BILLY: Bernie?

MR. SHIRE: I'm Bernie Shire and I'm with the American Association of Meat Processors and I just want to make a couple of general comments that it might be good to think about as everybody's working over all these specifics.

My background is in public relations and a while ago there were some comments made by -- about the fact that scientific uncertainty shouldn't prevent us from putting some of these things into effect to reassure the public. And I think that's a concern that people in the industry had and others as well, USDA too, for a long time. I think part of the problem is that this process and this plan has been sold as a way -- as a cure all that will reassure the public and just recently in the media, if you saw it, there were representatives from both industry and USDA agreeing that there are no clear answers to this situation. I think that's a danger in pushing this -- the way it's been pushed ahead, the industry basically had to fight to make sure that they would have a chance to say something. And if that hadn't taken place we wouldn't really have gotten to this point here. It sort of reminds me -- two weeks ago I was talking to one of the representatives of a consumer group that was here and she said to me -- you know -- she said if science discovered tomorrow that if you fed green jello to all the animals and they would be okay and there wouldn't be any problems she said I'd be out working for that and I think part of the problem is that there's this push in an effort to reassure people that this problem can be taken care of. Unfortunately, it's not going to be as simple as it seems. And I think that -- because of the pushing of some of the consumer groups and others that's the process that's being created.

The other comment is general too. It has to go back to the very beginning of this proposal that USDA said basically they wanted to shift from command and control to allowing the industry to have a more major role in providing us food safety. But throughout this whole thing it's hard to see that happening sometimes. What you see basically is the USDA debating, I guess among themselves, how to do this and, again, because of the pressure of the various odds, consumer and industry, kind of shifting back the other way. I don't see the real move as a result of this plan being made from command and control as much as it should be, as much as USDA says it wants to be. And maybe that's something that needs to be worked on. Thank you.

MR. GRUTT: Steve Grutt with the same outfit -- American Association of Meat Processors. I don't think there's any doubt in anyone's mind in this room that as we look at the interim steps that are being proposed or near term measures that the time temperature factor being proposed is the most single expensive item that we have on the agenda. We want to move toward a HACCP based system. And I think what many of you have said here earlier is we tend to detract from going that way and we quit looking at the product and I think we need to look at the product. This was said at the meetings two weeks ago. We don't want to lose that vision. We have to maintain that flexibility. When Gary Crane referred to the size of that animal he has to also remember and I think you need to be aware that many of these plants have one cooler and that cooler handles beef. It may handle pork, lamb, perhaps some poultry items. There are limitations and when you look at the question that was raised by a couple of people, has USDA looked at the scientific basis for the forty degree cooling thing, I don't think that was answered at all. But the other question was does the infrastructure within our industry -- is it there or is it coming on line with new plants? Now, folks like Jerry in a business a hundred years old building a new plant, they may be able to design some of that capability but there are an awful lot of plants out there that are located in towns that there's no more land around them, there's no expansion capability. We've got to recognize they've got limitations and need to maintain that flexibility. And we talked about the whole approach for these near term or interim standards or requirements. We all want to see something done. But when we lock in the specifics on each one we lose that flexibility and the same thing will apply here with the anti-microbial rinses, I say there's different versions of scientific viewpoints on all of these factors, but I think we don't want to lose the focus on that final product and I just hope we don't go down too far and throw all of the bucks that the industry may have to come up with on things that may not get the job done. That's our main concern. Thank you.

MR. BILLY: Katie?

MS. HANIGAN: Mr. Taylor, I have a question for you this morning regarding the proposal. It states here that carcasses and raw meat products will be maintained at an internal temperature of forty degrees or below during handling, holding, and shipping. Will you give us your definition of handling? Is that boning, grinding, etc.? What is

your current thinking on the temperature during handling now? You've outlined current thinking for carcasses. What about for handling?

MR. TAYLOR: I don't have anything in my head to add to the current thinking. It's an issue and I don't have -- I mean it's temperature during handling. We're still -- I mean that's still under consideration. I'd ask if any other members of the panel -- folks from the agency would like to talk about what's in the proposal and what the concept was to tell the definition of handling.

MR. CUSTER: Carl Custer. And handling would be all subsequent handling of the meat, whether it was grinding, slicing, chopping, breaking, packaging. That would be all total handling, processing of the product.

UNIDENTIFIED VOICE: Are you saying everything?

UNIDENTIFIED VOICE: Was that beef, pork, or all beef products?

MR. CUSTER: That's what was proposed.

UNIDENTIFIED VOICE: What's your current thinking?

MR. CUSTER: We're open to comments. We have a scientific basis that we published and we are open to comments and we have heard quite a few comments. I think there are many ways of achieving the same goal.

MS. STOLFA I just wanted to respond to a question that I'm totally responding to that several people have raised. As Carl mentions, we did have -- we do have a paper that, in fact, provides the scientific basis that went into the thinking of the proposal. I think that -- and we did an appendix to the regulation. It was available on request or it could be viewed with the other documents that related to the proposal could be viewed. And in retrospect, I think we felt that we were sorry that we didn't at least append it to the proposal, but also I want to make it clear that it seems to me that the scientific basis that's reflected in that document which is largely theoretical has been very usefully supplemented by the detailed comments that we received and so it's the combination of the -- where we started and the detailed comments that we received and that have been reiterated here today in certain instances that I think has pushed our thinking in the direction of the options that we tried to describe.

MS. MUECKLOW: Do you have a hundred and fifty copies of that paper?

MS. STOLFA: I think we could bring some copies of that paper out for the afternoon session.

MR. TAYLOR: Can I just follow up on Katie's question?

Let me just make an observation and then ask you for -- you know -- some further thoughts. Let me just reiterate what I think we've tried to make clear throughout the morning is that the proposal which, again, laid out specific time and temperature requirements for cooling had a performance standard alternative; that is, alternatives would be microbiologically equivalent, but it did lay out specific time and temperature elements. What we heard resoundingly in the comments was that the proposal overlooked the reality that there is a wide diversity of production practices, many of which are just flatly incompatible with the specific time and temperature elements. We hear that. Our current thinking is we need to change the rule to deal with that. So the paper attempted to convey that we're looking at alternatives that recognize the fact that the specific time and temperature elements in the proposal don't take account of the diversity and we need to deal with that. We need to change. Whatever we do, whatever decision we make, and there was a wide array of options on the table, we've got to deal with that diversity. If you've got -- I mean I would welcome here and in your comments following -- you know -- tell us what the rules should be with respect to temperature during handling or there should be no rule. I mean -- and if you've got particular observations in mind this is what we need to hear.

MS. HANIGAN: I appreciate, Mr. Taylor, your clarification. I guess I was sitting here afraid that we're focusing only on the carcass and forgetting that we still have our proposal in front of us and we hadn't talked about handling yet and I guess I have a lot of respect for Bruce Tompkin and I think he brought up some real valid points on what temperature requirements these different organisms need and I just want to make sure we're reminded we also had a handling requirement here as well.

MR. TAYLOR: Thank you.

MR. BILLY: Unless there's a last word --

MR. NEESE: Are you going to let me talk a minute?

MR. BILLY: Sure.

MR. NEESE: In our particular operation -- I'm Tom Neese -- we start with a carcass that's twenty four hours plus old at forty degrees. Process in a fifty degree room. In order to maintain that product at forty degrees we're going to be required to operate at roughly thirty

five degrees in that room because the mixing, the grinding, the packaging all add temperature to the product. Now, that is a problem, gentlemen, a very significant problem. Point number two, if we process that product at less than forty degrees we're changing the characteristics of the product. If we grind at thirty five plus degrees the characteristics change and then we're going to be required to hold the temperature at dry ice or ice. You change the characteristics of the product which is not good for us. We are DSD. Let's just take it a little bit further. We put it on a thirty two degree truck, we go to a grocery store and unload that truck at ambient temperature outside, wheel it into a warehouse that is non-refrigerated and move it into their cooler or their case. Their case will defrost twice a day -- go off for twenty to thirty minutes in order to be able to have refrigeration. The temperature is rising above forty degrees in that period of time. We just finished -- we put things in perspective. What our company will sell in a year what some of the companies in this room will sell in twenty minutes in dollar volume. But we just finished rebuilding our internal plant that was the oldest portion at a cost that was roughly four hundred thousand dollars. It is not built to process at thirty five degrees. It is built to process at fifty degrees. And we're very proud of the fact that we made the decision internally to go to the dirt and to the seaman joists to rebuild our plant but we cannot do what you're asking us to do. And, let's put it in perspective please. If you take a forty degree carcass and process it in an hour and a half time it's in a sub-zero degree freezer to bring the temperature back down to thirty two degrees. You haven't got the time in there for the bacteria that's on it to multiply. Thank you.

MR. BILLY: I'm ready to wrap this up now. It's --

MR. LOCHNER: I've got one more.

MR. BILLY: All right. One more point.

MR. LOCHNER: Lochner at IBP. This is a critical point that I believe has been overlooked, has nothing to do with chilling rate, but it does have to do with the time element on carcasses on a kill floor and it was overlooked because it should be, and I have it in my -- in our critical control point, when a carcass is railed out for pathology or railed out for another reason there should be a critical time limit set to make sure that it completes the process, whether you're -- it's the exception and not the rule -- but I have personally seen carcasses hanging on kill floors for over four hours or three and a half and it's

immaterial whether it's how long because the IIC was either in the line or not available to do final disposition. That situation has to be corrected and that is a regulatory issue that you did miss.

MR. BILLY: Okay. I'd like to thank everyone. It's about quarter to one so I'd like to resume at quarter to two. Thank you very much.

(A luncheon recess was taken)

AFTERNOON SESSION

#3 MR. BILLY: A couple of announcements. One is that the remaining -- all the remaining papers except for one on the trade issues are now available and on the table out here so if you haven't picked them up already please do so. The other is that with regard to the discussion this morning and there was a series of questions about the scientific or engineering basis for what was in the original proposal to the extent that people would find value in going back and looking at that in terms of the original proposal we have arranged to get a number of copies here and we'll let you know when they arrive. We'll put them out on the table as well. It's the paper that Pat referred to which was not a part of the proposal but was indicated as being available. So for those who would like to look at that we will have copies available for that.

I'd like to quickly wrap up the discussion on cooling. There have been a couple of suggestions that it might be possible to identify some more specific option based on all of the discussions this morning and Rosemary's been asked to be recognized to sort of lead off a discussion that will attempt to do that.

MS. MUECKLOW: Tom, thank you. I've spent thirty five years learning the art of political science, the only scientific class I passed with an "A" was microbiology because Dr. George York was the teacher.

We've spent a long time this morning defining the problem in terms of carcass cooling. It's a complex problem as we certainly learned that varies a great deal from plant to plant, animal to animal, end use of the product, and so on -- a very complex problem. That in the three and a half days of meetings that I've sat around this table, this has been probably one of the most productive discussions because there has been evident better understanding by all of the parties around this table for the different things that are going on and so maybe there's been a little movement by people. There are still a lot of unanswered questions but it occurs to me that we've asked a lot of questions as industry today, we have the best brains in this industry around the table, we have the best brains in the agency around the table, and we have other people who are not as intimately acquainted with how we operate our businesses also sitting around the table. This would be a good opportunity to see if we can put some frame to answering some of those questions that have been one of the most disturbing pieces of this proposal and see if we can give you as

regulators something hard and fast rather than having to go look through the transcript record and see what this one, that one, and the next one said. I'm not the person to give you that data but there are people around this table who know that data, who are scientists, not political scientists, who really do understand what we've been talking about. And I would urge that maybe we spend a little bit of time giving you the chance to see if you can draw that consensus rather than protract the discussion of what the problem is. We know what the issue is. We need to see if there is substantial view on what is a doable activity and what is an appropriate activity to bring this thing to finalization.

I know Dr. Nickleson also has some comments from a red meat hygiene paper.

Nick, would those be helpful as we look at this kind of consensus maybe? Sort of philosophical and I know he thought it might be helpful to offer those to you as we enter that discussion if that would be permissible. Think it would be helpful?

DR. NICKLESON: I think they are a viable option. They're something we certainly should look at. In the paper that was just handed out on the scientific basis for proposed cooling requirements the researcher that I'm referring to is represented in there five times -- Dr. Gill out of Canada. In a recent paper, Dr. Gill sort of explains why set temperatures for all commodities don't work. Such regulation does little, if anything, to assure the hygienic adequacy of carcass cooling procedures. And he gives some examples related to the size issue that came up earlier. Instead of just simply condemning that he offers an option and it's under a paragraph, Application Of HACCP To Meet Cooling Processes. The hygienic adequacy of any meat cooling process can be conveniently characterized by a temperature function integration technique -- what he refers to and he published in 1991. He's done this for beef carcasses, for hot bone product, for pork carcasses, and spray chilled carcasses. The technique involves the collection of temperature histories from the persistently warmest of the microbiologically contaminated regions of the product. And he's pretty much identified those and they should not vary from animal to animal.

Temperature histories from at least twenty or more units are selected at random and are sufficient for process characterization. These are then plugged into an appropriate model that determines the

number of generations E. Coli could go through under these temperature conditions. I don't think it includes the lag phase but a similar type model could be developed very reasonably. The integration yields a single proliferation value for each cooling curve with the values being conveniently expressed as numbers of generations. So he makes a recommendation in about you would not exceed "x" number of generations under the process that was in control. So a routinely collected proliferation data then could be used for the purpose of maintaining the process within the statistical control so it would be the monitoring process for that control point and that would be the data that would be available to show it was under control so I just suggest that maybe some more in-depth look at Gill's work might be an option to option two that was listed in the working paper. Thank you very much.

MR. BILLY: Any comments on what was just suggested? Yes?

MR. SHAY: Barry Shay, CSRO, Australia. My understanding of the work of Gill has one shortcoming in that it doesn't take into account the drying effect and while that may not be so applicable in your industry, in our industry we don't spray chill and the drying effect has a profound influence on the bacterial growth so I think that needs to be considered.

DR. NICKLESON: I'm not saying that his model would necessarily be suitable but I think it's something to work from as an example of what might work.

MR. BILLY: Dane?

MR. BERNARD: Thank you. Dane Bernard, National Food Processors Association. I think this graphically illustrates the kind of process that we need to go through. If you look at all of the performance standards that have benefitted us in the past those have come through development of the scientific consensus rather than just a simple review and coming up with a number. They're all over the place. The 70 that we talked about two weeks ago as the target for the cook on poultry. The 12-D that we used in the canning process. These are not numbers, however, that came without some consensus building and I think what Nick has offered here is a starting point for a good scientific discussion and I think we can build some consensus for adopting a performance criterion based on this kind of an approach. Thank you.

MR. BILLY: Caroline?

MS. DEWAAL: First of all, if Richard doesn't mind, Richard is a small business operator. Did you understand what the approach was?

MR. BECKWITH: Not really.

MS. DEWAAL: I didn't either. So as one of the less brainy individuals sitting next to a small business operator can you like give us what that means in like something that's like applicable to all plants?

DR. NICKLESON: It's monitoring the cooling time and temperature of the whole process. It would be like looking under the cooking curve of a product. Even though we were trying to achieve 212 there would be some heat applied to that process say at 120. This is the reverse and it's looking at time and temperature requirements or parameters within the cooling cycle and based on those times and temperatures when they're plugged into a known model that calculates the growth of E. Coli, I don't think it's 015787 but it's a typical E. Coli. And then it calculates the number of generations -- the number of times that particular microorganism divided and then you would set some limit that says we would not accept ten generations. We would not accept eight generations. We may be somewhere below. I don't know what those numbers would be but I think it's a very realistic means to customize cooling for each process and each product and still stay within the safety requirements of the growth of E. Coli and other pathogens.

MR. BILLY: Dane, are you going to add to --

MR. BERNARD: Let me add to that because I don't think that -- Dane Bernard, National Food Processors -- completely addresses the concern that's here. We use the same approach and if you look at what we did for cooking hamburgers, for example, we came out with a table that said -- you know -- the parameters that it takes to get there. We can do the same thing with this approach or the approach itself can be used by an individual processor to get equivalents and this is the term that's used in the proposal. Once we can achieve some consensus on how to do it -- on the approach and on the target -- we can come up with simple guidance for processors who don't want to go out and collect their own data and run through all of these calculations or once the pattern is set, we can use the pattern. So I think it's a starting point but it does have to made simple enough that it can have wide application and we can make it simple enough by running through the calculations doing some average modeling or, worst case, modeling if

you want to call it that, and come up with, okay, you can do it by the method here in the table or you can take the methodology and you can run your own data. So I think that it -- hopefully that answers really the concern if we can come to scientific agreement by consensus on the approach and on the target. Thank you.

MS. MUECKLOW: Tom, could we ask maybe Paul and Dell and Jim how they would feel about this, whether this might work for them?

MR. BILLY: Sure.

DR. MCKENZIE: Dr. McKenzie from New Zealand. If I could get a regulator's perspective, Dr. Gill, he was based in a research station in New Zealand and started this temperature integration work there and we used that sort of an approach to work out equivalent time temperature regimes to the one that was imposed upon us by the Europeans -- the seven degree one. So we're very supportive of that type of work as a regulator. Thank you.

MR. CLAYTON: Paul Clayton with Montfort. We wouldn't have a problem with that type of a system either. I've got to believe that we basically got that in there. We don't have any scientific documentation that's needed for that but I believe in our processes we're probably very relatively close to that. I have not personally reviewed that so some of my staff has but also I'd like to check to see how close we really do fall into that. Maybe we could support that.

MR. SHAY: I think one of the shortcomings -- Barry Shay, CSI, Australia. I think one of the shortcomings with that approach -- I think we've recognized it already is that it doesn't take into account the lag and we've had a lot of discussion this morning about the lag and it has a profound effect so I think we should proceed down this path with some caution and be very mindful of the inadequacies of that approach.

MR. BILLY: Are you saying the inadequacies of his specific model in the paper that was referenced or the general approach of developing a model that would among other things take into account --

MR. SHAY: The problem with the development of a model is to be able to predict the lag phase and I'm not aware of any models that are currently can cope with that.

MR. BILLY: Okay. Bruce?

DR. TOMPKIN: Yeah. Bruce Tompkin at Armour Swift Eckrich. Actually Colin Gill did develop such proposed guidance. It is based on broth tests. Their E. Coli isolated from carcasses and so their concern

about the dehydration, the significance of dehydration during the chilling process is not counted in. The idea of going through a computer model or, in this case, what he's done is a good basis to start from but it really -- it's conservative. I think that you may find that in reality in a given process you have less multiplication than actually maybe estimated here. So that's one of the problems with predictive modeling. You really should get in and verify it to determine whether, in fact, it's real or not. There was another proposal, incidently, to consider and that was one from Philadelphia expert panel which consisted of you sample at the beginning of the evisceration process after defeathering or after removing the hide and the total process in tracking E. Coli you would not see an increase in E. Coli levels. That allows you -- so you're addressing contamination as well as decontamination if you have it and also takes it through the chilling cycle with -- and that's another option.

MR. BILLY: Well, I see some questions. You want to elaborate on that a little more about what that recommendation was again and just --

DR. TOMPKIN: The latter one?

MR. BILLY: Yes.

DR. TOMPKIN: Well, the -- you might recall that there was a technical conference held in Philadelphia in May -- really May was part of the series of conferences that were held by the USDA and a number of individuals presented comments and then a panel was selected to condense those comments into a report and in the process they also were given the freedom to develop some recommendations and they did so. The panel was actually given an opportunity to come up with more than one set of recommendations if they disagreed. As it turns out, they reached a consensus -- the individuals involved -- and one of their goals then was that the measure for process control and that's what we're talking about in the example should be two-fold and the one was that the level of E. Coli on chilled carcasses shall not exceed the level present on freshly defeathered, dehaired, or dehided carcasses and then -- and that was the main one I wanted to address at this point.

MR. ALLEN: Bruce, the end point --

MR. BILLY: Dell, would you mind --

MR. ALLEN: In regards to that proposal -- Dell Allen here -- the end point then would be whenever they chose then to take this bird

and/or carcass on in for the processing would that be the defining point of the chilling process?

DR. TOMPKIN: It would be -- it would have been coming out of the chill tank or out of the cooler going to carcass breakup.

MR. ALLEN: The point I'm trying to get at -- would that address all of these different systems that we've talked about?

DR. TOMPKIN: Well, yes. It addresses the total slaughtering system. What we've been dealing with this morning is just one aspect. Do pathogens in fact multiply during the chilling process and what time temperature should be established to control that public health concern and so we're really dealing on that one whereas this other proposal and I think what we talked about two weeks ago was to track the total process and it comes back down to one of these options again.

MS. RICE: Kim Rice with Jimmy Dean. Bruce, where -- how would you handle an operation like our's -- hot boning? Not to put you on the spot. I mean --

DR. TOMPKIN: That's okay. I just sample the ground product period. There's no sense sampling carcasses. It's hardly in the carcass state. It goes right into grinding and making chubs or whatever. That would be the best sample too.

MR. MAY: The National Broiler Council supports the last option that Bruce was talking about there that came out of that hearing and the experts that ruled on that. We think it's a good one.

MR. BILLY: Okay. Mike.

MR. TAYLOR: So what do you think, Rosemary, do we have a consensus?

MS. MUECKLOW: I think we should wait and hear from Mr. Lochner.

MR. BILLY: All right. Sorry.

MR. LOCHNER: Lochner, IBP. On the concept, that goes back a little bit to what I mentioned this morning and that is it is a combination of engineering and food safety, the science behind food safety, and quality, and I don't know that there may be shortcomings with that approach but I think determining some type of maximum generation time to establish cooling but when Bruce Tompkin came back and talked about a total control point we're back to really the debate. Are we going to segment HACCP, are we going to go back to a total HACCP? And I think the agency has to decide philosophically that point before we continue to debate things or maybe we can debate them

and then he can come back and decide but total HACCP versus segmentation of control. But on Rosemary's specific point that Nick brought up, I don't know that I could say that we know the answer today but I think a group of people sitting down who understand the engineering of refrigeration, the chemistry and physiology of refrigeration as it relates to muscle quality as well as the microbial influence of chill rate in modeling could come up with a very good recommendation. My initial criticism is the agency did it without the input of all these disciplines.

MR. TAYLOR: It's never too late to get it right, Dr. Lochner.

MR. BILLY: You want to hear from Rosemary?

MS. MUECKLOW: Nick, I think, had something to ask first.

DR. NICKLESON: I don't want people to think that there are two ideas up for grabs here -- the one that I presented and the one that Bruce presented. They're both options. They probably compliment each other somewhere down the line and Jim's point is probably -- needs to be taken into consideration so it's not a vote between what I've talked about and what Bruce has talked about.

MS. MUECKLOW: I think that there is beginning to be some solid piece of mass that we can put our hands on but I think Lochner touches on the issue that comes back to you, Mike, and that is how are we going to fit these pieces in and HACCP -- and we need to know where you are and there are a lot of questions asked along those lines this morning and we need some precise sense from you because if these people felt there was something that they could work with and that it would be worthwhile my guess is that you could get something from them within a week or two weeks that would really make solid sense but if they're simply spinning their wheels because you've got some other idea over there on how we're going to go then -- you know -- they might as well save their time because they're busy people.

MR. TAYLOR: Why don't I just say where -- you know -- where we are and reiterate a little bit what we said this morning.

MS. MUECKLOW: We would like that. That's why I like to sit up.

MR. TAYLOR: And I will try to articulate this in terms that keep learned counsel in their respective seats so that I don't trample on the administrative decision. I have now gotten the attention of learned council.

MS. MUECKLOW: They're all awake and tell them I got a lemon drop for them if they're really good.

MR. TAYLOR: That would be wrong. As I said this morning, we have heard resoundingly the message that our proposed prescription of specific time and temperature parameters as though they were applicable to the full range of plans and took into account the full diversity of operations and technologies that we've heard resoundingly that that won't work. And because of those comments and because of our general desire to move to performance standards, not only are we -- our current thinking is that no one set of time and temperature will work everywhere. Indeed, again, our proposal reflected that because we said you could do a microbiological equivalent option. We are very attracted to looking at performance standard means of achieving this objective of having some measure of accountability for cooling. We've heard two different approaches and I think, Nick, that they're not mutually exclusive. One, if I understood it correctly, was developing a performance standard and at the cooling issue using Dr. Gill's work as a starting point and -- but recognizing that there would be more than one way to achieve some particular performance standard when it comes to growth. I mean that is essentially the second option -- you know -- in the option paper. It is an approach to -- it is identifying a particular source of sort of intellectual -- you know -- raw material to start with the frame a particular performance standard. We are very -- I mean that option is in here because we are very attracted to considering that. We also are interested in -- you know -- the Philadelphia option. I mean that is not dissimilar from the use of generic E. Coli as a process control indicator as we discussed two weeks ago. And so we're very -- you know -- seriously attracted to the details of how you would do either of these. So from our standpoint, I mean it would be extremely useful if before the close of the now re-opened comment period if the best thinking that anyone -- you know -- chose to pull together to be concrete in suggesting ways to pursue these alternatives to what was in the proposal would be very useful if that work were done and submitted -- you know -- in written form. It would be extremely useful.

MS. MUECKLOW: You mean it might receive really good favorable consideration in your office?

MR. TAYLOR: It would obviously be considered, Rosemary. We're looking for answers here. You know, there's no -- we're -- if I haven't been clear that we're looking for a different way to skin this cat I don't know how I can be more clear and I don't know the answer and I

can't endorse any answer on the spot. That's what the lawyers won't let me do. How am I doing, Doctor? And so, I mean, seriously, the more concreteness that folks all over the place can provide in terms of -- you know -- ways to carry out some of the concepts that we're identifying in these papers and, in particular, some of these performance standard alternatives, we really welcome that. And, including concreteness with respect to the question you identified of what's the relationship between developing such a performance standard and implementation of HACCP. I mean that's -- we're looking for concrete answers on that and these are the very issues that we -- you know -- we need -- you know -- we very much welcome substantive input. Because I agree with you, Rosemary, we know -- we know what the issues and the problems are with the proposal. I mean I think that was really useful this morning -- got that out -- but we would welcome any input we could get on what the answers ought to be.

MS. MUECKLOW: Well, I'm grateful to have the gentleman here on my left who is employed by an organization -- I'm not sure what they're name is today -- but he certainly understands these issues from an organizational point which is committed to helping a lot of people in the industry figure this kind of thing out and so I appreciate that. I appreciate what Dr. Tompkin said and maybe if these things are not mutually exclusive of each other and can indeed be considered as part of a flexible way to address this issue, again, we're back to the point that was made hours ago that no one size fits all in this industry and as we learn on the hot bone hog sausage issue, their needs are going to be different. But if we're beginning to hear from your office that you will really give very powerful consideration to what we can do as an industry that's why we're here today. That's why I flew the red eye and had another half hour on the Dulles bus this morning so that I could be awake all afternoon here today and pay attention and see if we could make some real progress. And I think we may be on the point of chalking up the first one on the board but indeed we found some commonality about how to proceed and that you might give it very favorable consideration. We realize you can't say yes or no today cause you've got your regulator but if we're close to that this is somewhat encouraging to me and I'd just to make sure everybody else around this table feels that encouraged. Well, they're into sub-meetings already.

MR. BILLY: Katie, on this point. Go ahead.

MS. HANIGAN: Katie Hanigan with Farmland Foods. We're now in day four of a six day meeting and we have identified numerous hurdles. We don't know if we're going to have segmented HACCP, if it's total HACCP, we're going to have micro testing if we need it, do we have the scientific basis, don't we. My question to you is, are you even considering putting together this proposal in one packet and getting it to us to look at before it becomes a final rule? Because we've sat here now for four days and we're no closer to agreement between FSIS, the consumer, and the industry. And I wondered if we're not doing something in haste setting a December 31st deadline.

MR. TAYLOR: The most direct answer to your most specific question is we haven't as yet considered that and I think we've been very clear that the purpose of these meetings was to have really substantial dialogue on the real issues which is what I think we're having. And -- you know -- we expressed our belief that -- you know -- it really assists the decision making. And that -- you know -- obviously there will be issues. To the extent that we are going in completely different directions, for example, if we were to on any issue, then it has been indicated so far by the process, the proposal, and the comments and all of this discussion, that would lead to some real departure not foreshadowed by -- you know -- what's going on. I mean there would be actually a legal requirement to so some further process. But whether there would be any practical -- you know -- I mean that's just a decision we reach -- whether there would be a practical need and value in light of the competing considerations -- you know -- to have sort of the process you've -- perhaps you've suggested. We just haven't reached that question.

MR. BILLY: I'd like to say one thing. Rosemary, you mentioned the idea of consensus and with respect to this process, since we're in the rule making mode and dealing with this in a way where -- you know -- there was an announcement of this meeting and people were encouraged to attend, there also -- the comment period is up and there are an awful lot of people not in this room, even though some represent many people there are still a lot of people who aren't here. We need to follow an approach that takes into account the comments that we receive from those who aren't able to attend as well so -- you know -- I think it's a discussion about identifying a theme or a strategy that people think has some merit that can be further flushed out and submitted as comment is a very productive kind of idea that I think

will help the process. It's a very -- you know -- because everybody's hearing the limitations and concerns and so forth. That's good. But we need to weigh views of anyone that chooses to comment as part of this overall process so I just wanted to make sure that's clear to everyone that we need to approach it that way.

MS. MUECKLOW: It is absolutely not my intent to usurp the authority of the Acting Under Secretary or the Associate Administrator or all the other fine officials I see sitting opposite me but it just seemed to me we spent a lot of time passing the ball around this afternoon and it's now time to say the game's just about up on this one, what is a doable event, and even though you might not get a hundred percent vote around here there might be some people who have some ifs, ands, or buts. It's good to give you some strong recommendations on an issue that there is relatively broad consensus as far as I'm hearing it. If I'm wrong then I'll hide under the table and eat all my lemon drops myself but -- you know -- I just want to see if we really are giving you some very powerful input of something that we can do. I don't want to go away from these meetings that everybody just kept just saying no we can't do that, we can't do this, we can't do the next thing. This is something that there is some reasonable understanding that it's a can do activity that would be helpful but we've still got some pieces to find out about.

MR. TAYLOR: And, again, there's a thirty day window here following the close of these meetings for submission of the most concrete possible solutions that you believe and -- you know -- would address the issues. We welcome it. I mean we invite it. It would be very helpful to us to get concrete ideas about these issues.

MS. MUECKLOW: Katie had some questions and I'm not sure I got that answer in my head yet. She asked you how this all fits together with all the other days. Isn't that right, Katie? Did I miss that answer? Was I sleeping?

MS. HANIGAN: Well, I guess I felt like Mr. Taylor answered my question. I think --

MR. TAYLOR: She didn't like the answer.

MS. HANIGAN: I guess I'm very much -- you know -- you sit here and you wonder what progress have we made. We have discussed a lot of things that have been very valuable but still not real sure if we have a segmented HACCP program or if we had a total program or if we're going to have salmonella testing or and/or E. Coli and I think when

you're coming through with this type of a regulation that's going to affect everybody -- the American consumer, FSIS, and the industry -- that it would be appropriate to put together the document and let us look at it, even the current thinking papers that we picked up this morning have three options and I'm not so sure if they're your current thinking after lunch after we've had the discussion this morning and that's why I asked that question.

MR. COOK: Charlie Cook with Cook and Thurban. I'd like to add a little concrete to Mike's suggestions there and the concrete part as I read out of the white paper here and these commentors recommended instead of plants addressing cooling curves it should be part of their implemented HACCP program. I would support that. What my concern is, there are as many types of product -- diversity of products -- coming out of a plant as there are plants and products. You have hot deboned product, as Kim alluded to, you have warm deboned product. You have part of the carcass which is hot deboned and part of the carcass which is chilled and you have all these combinations and manifestations. I think it would be absolutely impossible to come up with one set of model guidelines that would be applicable across the board. I think what is more appropriate is to let the HACCP plan rule the safety process involved here.

MR. TAYLOR: Thank you.

MR. POCIUS: Joe Pocius with the National Turkey Federation. I think that NTF would find either one of these approaches very acceptable -- far more acceptable than what was published originally. It gets away from a prescriptive manner into something that's a little more adaptable for the systems involved. I would like to have the opportunity, as everyone here, to discuss this with more knowledgeable people. For instance, one approach talks about minimizing the number of generations allowed and I have a problem imagining how that happens without taking in the fact of the lag phase but -- you know -- I haven't seen the papers so I'm making certain assumptions there based on my micro education. I think this particular point is important enough that if you stay on your deadline for December 31st that you might want to at least consider an exception for this issue so that we can all get together and discuss it a little bit more because there are some open issues that need to be resolved. For instance, this issue of a lag phase. I'd also suggest some time in the past I worked for the division of Reckon and Coleman and I know we

worked with Leatherhead in England a lot. And they did a lot of interesting work on this and they modeled out certain stability equations and it took into account Ph, took into account water activity which in the case of -- we heard before on the surface drying that would be accounted for, takes into account temperature and a lot of other things -- salt -- lot of things. So it can be adapted. These equations can be adaptable. They are not hard and fast. You have to go to the real world and you have to do testing. But they are directional and they work. You might want to check with Leatherhead as well.

MR. TAYLOR: Thanks.

MS. MUECKLOW: Tom, we're having some copies made of those papers and on your copy machine and they'll be down shortly.

MR. BILLY: Consider it part of our HACCP assistance program.

MS. MUECKLOW: Not like that 500 page document that we had to pay forty bucks for.

MR. TAYLOR: It's a bargain.

MR. BILLY: I'd like to move on now to the next item on the agenda which is anti-microbial treatments in slaughter plants. Once again, I'm going to ask Pat to briefly -- very briefly go through the paper that was provided and highlight the key points in the paper as the basis for our discussion.

MS. STOLFA: Hopefully you've all had a chance to look over the issue paper on anti-microbial treatments. You will recall from the proposal that the objective of this near term measure was to get all plants involved in anti-microbial treatments and using recognized technologies as anti-microbial treatments. Given that, we all seem to agree that even the best preventive approaches are not necessarily going to always result in pathogen free carcasses and so the notion behind the anti-microbial treatments which we know some people have been using aggressively was to broaden the use of these approaches in the industry by requiring that each establishment use at least one anti-microbial treatment. We went on to prescribe some limitations on where in the process the one recognized required treatment could be used. The proposal also described a number of potential anti-microbial treatments. Predictably, the comments ranged widely. Some people definitely -- you know -- thought this was a good idea. Other people objected among other reasons because of the prescriptive nature. People became concerned and reflected in their comments about one type of treatment or another. Some had objections to hot water which

was discussed in the preamble for various reasons, some had objections to organic acids where other people had some broader concerns about efficacy standards that we would establish, whether that was appropriate, whether one could make it through the thickets of getting to be a recognized anti-microbial treatment under our procedures.

I would direct your attention to the options. I would say I think we still believe that our original objective which was to stimulate and broaden the use of anti-microbial treatments as part of the slaughter process under present situations is a legitimate objective but I would direct your attention to the options that reflect our current thinking in this area.

The first option is probably the one that is closest to the proposal and that is we would continue to have as a near term requirement the use of an anti-microbial treatment but we might make some adjustment in some of the parameters around the use of that anti-microbial treatment. For instance, we received a fair number of comments that people objected to the limitations on where in the process they could be used. And so that changing the timing of application would be one of the more specific ideas which would fall under the first option which we are now considering.

The second option which we're considering, again, would have as a general near term requirement the adoption of an anti-microbial treatment but it could provide for an exemption for companies that were able to demonstrate that they met the elusive microbial or pathogen reduction standard which we've been discussing for two weeks. But if we had established a target and people in the near term demonstrate that they were already meeting that target option number two says that such people would not have to add an anti-microbial treatment so that if you wished to go through the process of saying, hey, I'm already at the target, I don't have -- I don't use one, I don't really want to change my process, that falls under the parameters of our thinking for option two.

And our third option is not dissimilar from options that we've discussed before and that is perhaps we should identify a performance standard for either generic E. Coli or salmonella or perhaps under certain circumstances both and it's -- you can get there any way you see fit and therefore if you chose to use one or more anti-microbial treatments that would be fine. If you chose to simply have better

preventive controls that would also be fine. If you chose to figure temperature controls as we discussed under the previous item that would also be fine. All we would focus on would be to make sure that you achieved the performance standard so these three options represent, I think, the range of our current thinking on the subject of anti-microbial treatments.

MR. BILLY: Okay. Comments. Jim?

MR. HANKES: Jim Hankes, small meat processor. As we venture into this discussion we have some expertise in this room. I would appreciate it if probably for all of us if you could focus on the different treatments and maybe how they'd reflect or relate to a small processor as far as their effectiveness. I know in the trade magazines what information's out there there seems to be a lot of debate over which ones are most effective but I guess I'd ask people in the room if they could -- you know -- keep us in mind during this conversations.

MR. ELFSTRUM: My name is Jim Elfstrum. I'm with the company called Rome Palank and in response to that question maybe I can give you a summary of where we stand vis a vis TSP in poultry and beef processing. Might give you some perspective of where we are and where we're going. We had been utilizing this technology for a number of years. It's been approved by USDA by interim rule making for the last two years. It's been approved for pre-chill as well as post-chill application in poultry and we have a petition in for approval in beef. We have conducted tests in many poultry plants. We have sampled 15,000 poultry carcasses during the last several years representing about 10 million commercial poultry carcasses going through these operations. So we have a long history of testing in the efficacy and the safety of this material. By the way, trisodium phosphate is grass. It is grassless substance and generally recognized as safe by FDA. It is approved as an in-process control agent and does not require labeling in view of that situation. There are no residues on the finished product.

The process that we have adopted in these plants has been proven to be very successful, it's very reliable, it's accomplished by means of an inside/outside body wash in the case of poultry and it works extremely well from day to day.

Our observations regarding all of this testing indicate a high degree of variability in these operations vis a vis microbial load on these products. It is clear to me looking at all the data that there are

good days, there are bad days, there are good hours, there are good minutes, there is a lot of variability. So I think it begs for the need for some sort of anti-microbial rinse to reduce the load going into the chiller in particular so that that chiller, whether it's beef or poultry, has a uniformly reduced microbial load into that operation. So, in that respect, it is an excellent HACCP critical control point. It is the critical control point for the microbiological perspective. By the way, I was involved in HACCP back in 1976 for a former company called Stouffer Chemical Company with FDA. So I know what HACCP means. I know what kind of documentation they require to accomplish that kind of process control in an operation.

So there is, I think, in the poultry business and all of these businesses, some degree of problem associated with maintaining uniform quality. This kind of a process, whether it's TSP or lactic acid or whatever will reduce that load into the chiller.

We have accomplished dramatic reductions in terms of salmonella going into these chillers anywhere from ten percent or even in some of the good plants that vary from zero percent -- we've seen days where we can't even find salmonella -- all the way up to a hundred percent on some of the bad days but if you use an anti-microbial rinse that product going into the chiller has dramatically reduced salmonella load into the chiller. And we've looked at chiller overflow rates from these operations and you can confirm and validate to reduce microbial loads going into the chiller by just looking at the overflow rate out of the chiller from a microbiological perspective. So it works extremely well and from an anti-microbial perspective, from a pre-chill point of view, we have approval for post-chill but in terms of poultry operations that's a much more complicated place to apply this type of technology. Pre-chill is much easier point in the process.

We also provide -- you know -- a good means of validating our operation in these plants we're in right now. We go in on a regular basis and validate and verify what is happening in the plant and we get the levels of reduction that we hope to achieve. So, in other words, we believe the process works extremely well, it's cost effective -- about two-tenths to three-tenths of a cent per pound of product -- and we have done focus groups with consumers. They're certainly willing to pay more for a product that has reduced microbial load and has an improved safety profile or at least the chance of improved safety. That is not a problem for them in our groups.

So I appreciate this opportunity to comment, give you a briefing on where we stand vis a vis TSP in poultry. Thank you very much.

MR. BILLY: Bob?

MR. BIDDLE: Robert Biddle, Australia. I'd like to express support broadly for the second and third option presented in the paper before us this afternoon. In written comments that we have submitted previously, we have, I believe, pointed to the need for flexibility in this area. We have, as already mentioned in earlier interventions, seen as a key outcome the definition of an objective. Is it, for example, an overall process outcome which leads to no more than an increase in "x" the numbers of E. Coli. We've heard various parameters about that today. Is it eight generations or one log ten or what is it? With -- -- it's one log ten. What is needed, in our view, is the flexibility to meet that objective for the range of processes that are out there and being used in the industry. There's hot boning out there. It doesn't fit very well with quite a number of the available technology such as hot water decontamination, for example. And there are a lot of practical considerations about the application in a near term perspective about a range of these matters. If the objective is clearly defined the industry, in our view, can look at a range of options for achieving that objective. Is it a hard tough chilling regime? Is it a specific decontamination process? Is it in some circumstances both and necessary? All these options should be available in our view and provided the outcome is achieved then the objective of the proposal is being met at a fundamental level. And for that reason we have suggested as much flexibility as possible in the application of this technology.

There is a further very important aspect in our view if it is the intention to proceed in a near term perspective with this technology and that is much of it is still at the experimental stage. You cannot go to a commercial supplier of equipment, buy a decontamination cabinet to treat the small start carcasses, at least I'm not aware in our country that you can. I haven't seen cabinets advertised or other equipment advertised expressly for hogs or for mutton carcasses or whatever. There are some units available for beef cattle. Many of them are still experimental and unvalidated under day to day industry conditions. And we believe that this is a further reason why the final rule should provide as much flexibility as possible. Thank you.

MR. BILLY: Caroline.

MS. DEWAAL: I raised this concern before. Given that we've changed from considering -- I'm sorry -- this is Caroline Smith Dewaal with the Center for Science in the Public Interest. Given that we are considering a change, at least, in the verification organism from salmonella to E. Coli -- generic E. Coli -- I feel like I need to articulate this again.

I am concerned that you not set up a system where companies can manipulate the outcome -- the verification outcome by using an anti-microbial rinse which is very effective on the organism that's being used to verify the process but not effective on the pathogens of concern for the product. And so in -- we have supported the use of anti-microbial rinses where they're deemed effective and I -- you know -- I can see that the Department's looking at alternatives with option two and option three which give more flexibility to the proposal which we don't oppose -- a move towards more flexibility. But I do want to make certain that you not set up a system which can be easily manipulated so that the verification goals are met without the pathogen reduction goals being met.

MR. BILLY: Ron?

MR. PRUCHA: Ron Prucha. I have a question. Does the agency consider the act of trimming as currently being practiced, I guess, on beef in the zero tolerance program, but is the act of trimming considered to be an anti-microbial treatment of itself or are you just considering the rinses of various types as acceptable anti-microbial treatment?

MS. STOLFA: We did not discuss trimming as a recognized anti-microbial treatment in the proposal.

MR. PRUCHA: There have been some studies though. I believe USDA studies even that shows that trimming in and of itself has a positive effect. Since there's so many small establishments that are represented and whatever, if they would come up with a very close trimming program and certainly washing but even washing with water, which everybody else does, would that be an acceptable proposal?

MS. STOLFA: It might be sort of -- we might be splitting some hairs here. What -- in the proposal what we discussed as were things that we had historically looked at as interventions that had an anti-microbial effect. Generally, at least in our thinking, those were different from what we might recognize more as preventive practices or the more traditional practices that were part of slaughter and

sanitary dressing and so we did not put trimming into the anti-microbial interventions and I don't know if that matters.

MR. TAYLOR: Let me just sort of -- Mike Taylor -- just reiterate and maybe say in a slightly different way what the premise of the proposal was. Trimming is obviously currently the required technique for moving visible fecal ingested milk contamination from beef carcasses as you know. And the proposal took that as a given and articulated the view as sort of a premise for considering mandating an anti-microbial treatment -- a recognition that currently prevailing techniques from removing visible contamination such as trimming -- we all recognize we still have an issue with regard to harmful bacteria remaining on the carcass and the premise of the proposal was that there's an available technology out there that when added to current trimming procedures can have the benefit of reducing harmful bacteria so, again, the proposal started from the status quo which is trim to remove visible contamination and proposed to add some additional anti-microbial treatment to it.

We've announced a meeting, as you may be aware, October 23rd and 24th, a two day meeting to address the so-called wash treatment issue and welcome your participation in all the issues about the utility of treatment and relationship to it and combination with other treatments would be very much -- I mean that's the subject of that two day meeting.

DR. MCKEITH: I had one question to ask the group. I'm sorry -- Floyd McKeith. Does the decrease in the normal flora from an anti-microbial treatment have a potential of increasing the risk of pathogen growth? In other words, when we use an anti-microbial to produce normal flora growth are pathogens more susceptible to grow or have less competition?

MR. GAINES: Bill Gaines, USDA. We have considered that numerous times before the proposal was published. Any time you reduce the number of bacteria on a carcass depending on which bacteria you've reduced those that remain may have a competitive advantage. However, in the proposal, we have not identified or had no evidence suggested that any of those in the proposal would create that -- Craig -- what you just suggested.

Do you have any information to the contrary we'd like to see it.

MR. ALLEN: Dell Allen. I'm with Excell. I think I mentioned this last time. We have had, I guess, a pretty good evidence because of

personal experience of such a problem, not necessarily with pathogens, although that's an unknown deal but several -- two -- three -- four years ago -- I don't remember what's been done since -- we had an approved test on lactic acid sprays for carcasses going into the cooler. It showed an effective reduction in the micro flora going into the cooler. We were operating it for about three months and all of a sudden we figured out that we had dramatically changed the micro flora in the cooler to the point that we were having all kinds of spoilage type problems on the product coming out the fabrication floor with blown bags and gassy ground beef -- all of that type of things. We were actually increasing our lactobacillus content in the cooler and creating an environment in order that they just basically took the cooler over. We shut the lactic acid spray off and very shortly the problem went away. So we do have these other problems as you introduce some of these type of preventive systems. We have to learn as we go.

MR. GAINES: Bill Gaines again. We have heard your story regarding that experience and, again, we considered that in coming up with a proposed reg. The proposed reg, however, proposes a use of organic acids at levels that have been successfully applied by other companies so it is something that can be successfully applied by some companies. There's a little bit of an art to this as in any other process on the kill floor but there are some other options available there also for those who have a little trouble managing the organic acid applications.

MR. BILLY: Jim?

MR. LOCHNER: Lochner, IBP. I'm going to probably take a different approach than most in the industry but that's not too unusual in some cases. My point is that if a anti-microbial is proven to be effective it will reduce the probability of enteric pathogens carrying into the cooler it should mandate it. Taking into consideration the key point is we got to determine appropriate efficacy. And also taking into consideration that I don't believe in the end what the equipment suppliers and the other entrapaneurs in this country that small business will have a disproportionate cost for that mandatory anti-microbial. I know that flies in the face of HACCP from a philosophical standpoint but I'm dealing only with the practical aspect. If we can reduce the probability of enteric pathogens on product we best do it.

MR. BILLY: Charlie?

MR. COOK: Charlie Cook. Early in the year in response to a question that the agency took the position that an effective anti-microbial affected a one log reduction in an organism, is that still the position of the agency's taking to define an effective anti-microbial?

MS. STOLFA: As indicated, again, I think several of the options -- the notion of efficacy and agency's involvement in defining that and requiring certain -- that certain kinds of things be done to demonstrate efficacy that's on the table for review. The proposal suggests a one log reduction but certainly we have been open to other kinds of suggestions. For instance, if an anti-microbial were found that were phenomenally successful against an organism like E. Coli 015787 but it would be difficult to demonstrate a one log reduction I think we would not want to be in the position of not taking advantage of whatever could be found in that area so when we talk here about this efficacy issue that your comment is pertinent for that. We have historically tended to use as a rule of thumb a one log reduction for the bacteria of concern.

MR. COOK: My concern now addresses compliance part of this because you may have addressing the hurdle concept of anti-microbial activity you may have an anti-microbial treatment that affects no reduction, however cinergistically it may work with one subsequently down the line that does have some anti-microbial and I think, again, you've got to have this total flexibility. What is the end point that you're trying to get at? And I think you need to address that in a broad concept of a HACCP plan there. Again, I think one has to consider another question of the agency's giving consideration to an operation that goes from slaughter directly to thermal processing for the whole carcass or animal. Does that carcass have to subject to these anti-microbial treatments or can that process get an exemption? It's going through an anti-microbial. It's going to produce ready to eat product down the road so how far are you going to define the anti-microbial treatment?

MS. STOLFA: As I say, I think that the options that we've laid out here reflect more current thinking which attempts to build in flexibility to address the points you and other people have made here and through the comments.

MR. COOK: Then how do you measure compliance against the flexible approach?

MR. TAYLOR: Well, let me just one -- this is Mike Taylor. The

issue of how you would apply an anti-microbial treatment requirement, whether it's performance standard or command and control, or whatever, is setting in which product is going directly to a kill step. I mean that's an issue that has been raised in the comments and obviously we need to address. What is the utility of that? What does that -- if we are going to stick with -- you know -- some approach like we proposed we'd have to consider that question. We don't have an answer to it but it's obviously a very legitimate question.

MR. BOYLE: This discussion gets to what I think is the heart of the conflict, if you will, and what seemed to be diametrically opposed objectives, both in terms of the point in the process in which you might be establishing performance standards as well as near term objectives versus a long term HACCP based system. A few examples come to mind. Let's say you do have a performance standard of no more than a one log increase for time and temperature requirements and let's say you have a performance based standard that you've alluded to but not established specifically for the end product. Well, let's say under a comprehensive HACCP based program a company can meet the end product performance based standard with a two log increase during the time and temperature part of their process. Is that an invalid HACCP plan? Is that an adulterated product even though it meets the finished product standard or guideline? Similarly, with the use of a microbiological -- anti-microbial treatment you're talking about a one log reduction perhaps as a standard of efficacy. Well, let's say you can demonstrate that. At that part of the process you achieve the one log reduction by spraying or using TSP but you don't meet the finished product standard or the more complex compliance problem is, let's say, you don't achieve a one log reduction with TSP, but you promulgate a finished product standard or a guideline and the finished product meets that guideline with an ineffective anti-microbial treatment or maybe without any anti-microbial treatment. What kind of -- where do you stand from a compliance perspective?

And, I guess, it goes back to the conflict that exists between the agency establishing standards at various critical stages in the process as opposed to a finished product standard or guideline. Is the objective to get it right at various incremental points or is the objective to let the industry get it right with the final product? If the goal is to get it right with the final product then adopting a program of near term mandates and long term HACCP is inconsistent with that objective.

MR. TAYLOR: I appreciate your comment and it helps frames the dilemma, if you will, that we're grappling with on the issues that we've talking about. And it really does have to do with the relationship between the finished product performance standard or a performance standard that would be an attempt to provide accountability for process control adequate to achieve a certain standard of performance. That's the concept we're talking about with the targets for pathogen reduction, salmonella, and so forth. What's the relationship between those performance standards and standards or requirements that we might apply to points along the way and the process to get there. And here's the dilemma in a nutshell. I'll use salmonella in poultry just because it's so easy to illustrate the point, Ken. I apologize in advance.

Here it is. We've got in our survey that says twenty -- twenty five percent of the carcasses are positive for salmonella at low levels quantitatively but positive -- you know -- significant incidents. We also know, using available technologies, that some plants are achieving incidents way below that -- five percent some would say. Some say using TSP they get zero or they don't -- you know -- we're not quite there yet on the zero hypothesis. But the point is that we know with current available technology some companies are achieving levels well below the mean. We also know there are companies that are achieving levels way above the mean. When we talk about interim targets for pathogen reduction we recognize that it is not feasible -- it is just our encountering and kind of recognizing the reality of the world as it is today -- it is not feasible in the near term to get all of those in the bottom twenty five percent up to the top twenty five percent, even though, again the folks who are doing much better who are at the top quartile are using currently available technologies, we recognize that we can't overnight bring the bottom quartile up and that's when we proposed our interim targets for pathogen reduction we proposed as a starting point for considering that bringing all plants to the knee within some period of time. That's an interim target for pathogen reduction that doesn't reflect our sense of what's good enough in the big picture and for the long term because when you know you can achieve well below that with available technologies that suggests where we need to be moving. As a practical matter in the relatively near future it's hard to picture pathogen reduction targets that are rigorous enough and just in light of reality that we could adopt and are rigorous enough to bring everybody in the near term where we'd like

eventually everybody to be. So then the question is, in light of the fact that our finished product standards are reflecting that we're in the transition mode when it comes to pathogen control and reduction how do we insure in the meantime that we don't backslide? How do we avoid a situation in which by adopting that target, for example, we create on the one hand an incentive for -- you know -- the companies are already achieving well below to not be using available kinds of technologies and on the other hand when we know there are technologies out there that are working today to improve the safety of product like anti-microbial treatments and recognizing that as a practical matter a performance standard is not as rigorous as it might some day need to be, how do we -- you know -- how do we move people along towards achieving that performance standard? If we're in the mode of having public health based performance standards where we know that the target -- the standard -- is a true food safety public health standard then that would be a different issue. Then you would be far more free to say that's the standard and we don't really care how you get to it if you produce a product that's safe in accordance with that public health based food safety standard for pathogen we'd be much less interested in how people are doing business. I mean HACCP would still matter, process control accountability for that would be important, but we'd be much less interested in do we need a performance standard for cooling, do we need some minimum standard of care when it comes to anti-microbial treatments. But that's our dilemma that we're in a transitional mode when it comes to a long term strategy for pathogen reduction. I think everybody agrees that over time we'd like the industry to across the board be operating with the best available technology and what's achievable but we can't get there overnight so this is -- we're trying to balance being realistic about setting targets for pathogen reduction that are achievable in the near term but also seeing to it that we're setting some minimum floor that insure that we're making progress. So that's the dilemma. And, again, we're in the mode of trying to figure out how to resolve that through the right mix of finished product standards and perhaps performance standards for some of the intermediate steps. That's the issue.

MR. HODGES: You see it as a dilemma. I don't. You say how do we make improvements. Well, we make improvements by taking step by step and implementing a HACCP program with all the principles that

you put in place and making that predominant factor of the focus of your inspection program as well as the plant program. An example -- anti-microbials -- to mandate anti-microbials is a continuation of the same kind of regulatory philosophy that you've had for -- you know -- for ages. If you simply look at it in terms of saying the industry should do what they need to do within the context of a HACCP program, anti-microbials in and of themselves might not be needed. You might have a hygienic dressing system that does not mandate anti-microbials. It's the same kind of argument I was making earlier this morning when I was talking about the time temperature issue. If you have -- in your validation process you have to have data that says the processes that you have in place are efficacious. I would expect the agency to evaluate that through the same kind of validation process. You will make a determination whether or not the HACCP program is acceptable or it's not acceptable. You will make that on some kind of criteria. If you make a determination it is not acceptable and that HACCP program is ultimately pulled that's your ultimate regulatory tool. It's not the standard that you set at some place in the process or even the microbiological standard that you set at the end of the process.

MR. ALLEN: Dell Allen at Excell. I'd just like to ask Mr. Taylor in the case of our's, what three plants routinely in the analysis of ground beef which we take samples per day, three per shift, and accumulate the data, are below less than 10 on E. Coli -- generic E. Coli. Are you going to make me, with that general record, put an anti-microbial treatment in those plants and expect any kind of a reduction cause you're not going to get it -- any kind of reduction on that?

MR. TAYLOR: That sort of scenario is why we've got on the table a performance standard option which says that if you're meeting some acceptable performance standard, whether it's generic E. Coli as a process control indicator or pathogen standard, I mean we need to consider that as an alternative way. I guess -- how are you -- do you all not use anti-microbial treatments in the process leading to that?

MR. ALLEN: None whatsoever.

MR. TAYLOR: I mean we -- you know -- this is a -- we don't have the answer here. That's why I do consider it a bit of a dilemma because there's a very strong rationale for our not mandating -- you know -- specific activities if a company's meeting an acceptable standard and the more we're confident that we've got -- we know what

the acceptable standard is the less we feel we need to consider -- being concerned about how that standard's achieved.

MR. BILLY: Paul, Caroline, Dane, and Terry, and Patrick, and Rosemary. Sorry. Paul?

MR. CLAYTON: Paul Clayton with Montfort. First of all, I just want to say that in all argument -- not argument -- discussion that we have here today I think some of the root things we need to think about is that we have to have science define what these are first and a lot of times what happens when science defines this is that they set the operating parameters for us. And that's important. I may choose as an operator to use several in one plant and I may not need to use as many in another. So I need to have that flexibility. And that may be because of a lot of reasons. But the thing is, inherently, science has told us we have to do that and I think that's a key issue we've got to keep in mind. So I would prefer that these things be attached to HACCP programs.

The question I have for you all is that has the current thinking or role of current thinking changed -- let me just put it that way -- relative to validating this science? You know -- today we have to revalidate all the science in every single plant when we want to install one of these procedures, if you will. Is that going to change? I don't think any of us have a problem with that. The thing is is what's right and the proper way to do that keeping in mind that all science does is define to us how we should operate these parameters so -- and I don't need an answer -- I think that's something you should consider. How is going to be validated for us to use these and, if so, can we use them in various combinations?

MR. TAYLOR: Paul, my concern here is that I directly answered your question or misconstrued your question. We're moving from a mode in which you are required to come to us for us to evaluate and validate that based on your offering up evidence and so forth to a mode where under HACCP we would be pulled out of the business of engaging in prior approval review of particular applications and -- but holding the company responsible for having validated and its effectiveness in the context of the facility's HACCP plan. And that's the direction we're moving in which doesn't mean you don't have to validate it but it is a plant responsibility within a context of HACCP. And that's why we're moving towards eliminating our prior approval system as much as we can.

MR. BILLY: Caroline?

MS. DEWAAL: Caroline Smith Dewaal, CSPI. I've heard a number of comments this afternoon that remind me of the HACCP as religion problem that we have here where -- you know -- we've got a lot of preachers of the HACCP doctrine and there are a lot of very respected people out there who I have a great deal of respect for. I need to simply remind you that we don't know yet how HACCP is going to work on these products and I, for one -- there is a tremendous transition going on in this industry between -- from a total command and control system to one which is far more permissive. We have supported HACCP cautiously with concern about great accountability built into the system. I am still not convinced that that accountability is in this program yet but we are working -- I've been here through many meetings, through the entire five month comment period working on trying to get consensus and I've been to all of this and I just -- it is frustrating for me to hear the industry over and over again say, oh, just give us HACCP, that's going to solve all our problems, and then -- you know -- we don't need temperature mandates, we don't need any other mandates, nothing, command and control. Just give us HACCP. We don't buy it. You can -- we'll accept HACCP within parameters but I just need to communicate that this HACCP as religion doesn't work yet and at some point maybe we'll all be in that church or at that synagogue but right now we really -- there is a process going on here and we do not support HACCP as a vehicle to deregulation of this industry.

MR. BILLY: Caroline? Sorry. Dane?

MR. BERNARD: Thank you. Dane Bernard. I left my collection plate at home. Otherwise, we'd get it started right now. Dane Bernard, National Food Processors Association.

I'd like to remind you, Tom, that Caroline has more hair than I do so you don't make that mistake again. There must be time for a break.

MR. BILLY: You keep commenting there may be quite a long time.

MR. BERNARD: Am I being cut off now? Option two here. Let me get out of the religious mode and on back to the comments. Option two very closely parallels some of the discussions we had, I think, two weeks ago. And let me summarize our position. If a company is using an effective -- and underline the word effective -- anti-microbial and however you want to define that -- there is a performance criteria built into how we judge an effective intervention. Let's take for example carcass washing since it's come up or these steam tunnels if

the companies who are selling there's ever get around to delivering those. There's a proper way to operate those and there's performance criteria in terms of achieving the specified result in terms of log reductions to provide a perfect opportunity to plug them into HACCP and monitor the parameters that give us the correct performance from those units and it's a very nice fit. On the other hand, if you have an operation such as Dell Allen has referred to that's already producing excellent results there isn't any need to mandate another layer on top of that. However, if you are not using an intervention and you have something that you can actually monitor and have verified and prove through the monitoring that you're getting a certain result then there is probably some need, as Jim Lochner said two weeks ago, to find out where you are and you do that through some microbiological testing so that you know what you're current performance is and that can be compared with baseline data. Now, having said that, I'm certainly not advocating microbiological standards for end product because when you do that, as I've said over and over again, you run the risk of having that become the goal post rather than the process control and continuous improvement that we hope to get out of HACCP. But is there a place for microbiological testing? Yes there is. It's the type of testing I think that at least I hope that Caroline and others will accept as the type of evidence that HACCP is indeed working in giving us the kind of product that we want. But, again, the bottom line, should we mandate interventions? No. I don't think that's necessary. We have never thought that's necessary. To achieve a level of performance is really the bottom line and there are a number of ways to get there. Thank you.

MR. BILLY: I have several additional names. We've gone about an hour and forty five minutes. Shall we break?

(A brief recess was taken)

#4 MS. MUECKLOW: We'll miss some valuable input if we don't let him talk.

MR. BILLY: Yeah. Maybe you ought to talk about your priorities here. Go ahead.

DR. MCKENZIE: I apologize but thanks very much for the opportunity to talk. What I was wanting to do and want to address -- I think it was Karen's intervention down there about the dream of HACCP -- in our country, and, again, I'm coming from a regulator's perspective, we've got quite a -- it's a slightly different program than

your own and we've been looking at dressing procedures, cleanliness of livestock before slaughter, and although we haven't replicated the microbiological baseline survey that was done in the U.S. a couple of years ago, we're finding that our bug counts are between a half and one log lower than your's so I think that demonstrates that in a beef sense to a limited degree. An interesting one is the research that we're doing. Again, we're doing this as the government just to help industry figure out exactly how the HACCP is going to work. But what we're finding with lambs is that the key criteria about the fleece, whether it's short wool, long wool, clean wool, dirty wool, wet wool, and dry wool, and if you get the short clean and dry and given a prerequisite GMP program on your slaughter line we're finding counts of ten to the one ten to the two and if you get it wrong it doesn't matter what you do on the slaughter line we're finding ten to the fourteen to the five. And I think that's how HACCP does work. I guess that around the table are a lot of the various industry groups seeing similar sorts of work themselves in their own internal R&D but I think when you get into HACCP you've got to put a lot of effort into R&D to actually find out these sorts of things that in a way they go against what we -- what I think are veterinary good manufacturing practice which is a unique brand of science in itself. Thank you.

MR. BILLY: Thanks. Terry?

MR. LEIDY: Terry Leidy from a small to medium size pork slaughter plant. I understand the proposed rule says all species. I was just curious if the agency has really established that in dehaired hogs, if the risk is there, and if that means all meaning them also. That was one question I had and also multi-specie plants, if the know how and the technology's out there for different size cabinets would you use the same treatment? How would they adjust to that? What are our time frames? And in our locality I would be curious how we would handle a DER or EPA issue with waste treatment of the water that comes from the treatment. Which agency is going to overrule and how are we going to adjust to that?

MR. GAINES: Bill Gaines. Would you repeat the first part of that question again?

MR. LEIDY: Yes. We're a smaller pork producer that slaughters and I was curious on dehaired hogs, not skun, if there is a problem not anti-microbial washing of hogs that's been established?

MR. GAINES: Has there been a problem with -- I'm afraid you're

going to have to tell me one more time with that. The way you're phrasing it I'm not following it.

MR. BILLY: Go ahead Jim.

MR. LOCHNER: Lochner with IBP. There's an excellent article by Colin Gill that says yes.

MR. BILLY: Were there other parts of your question?

MR. LEIDY: Yes. Different species, cabinets, and waste disposal.

MR. GAINES: Regarding who would overrule regarding the disposition of F fluent I think is probably the core of your question. We have no authority to overrule any requirements by the states or local boards of water quality. Neither do we have any authority to overrule what's required by EPA. However, there are plants who are using the types of anti-microbial treatments that are being proposed who are not having significant problems in that area. They're able to meet the requirements placed on them.

MR. LEIDY: Once again, I'm concerned about the size of the operation. I'm concerned that the real big people who have the technology and the resources.

MR. GAINES: I understand.

MS. MUECKLOW: Tom, another friend who's off to catch a plane.

MR. BILLY: Hold on. He also asked about different species.

MR. LEIDY: For instance, one kill floor might kill hogs, cattle, lamb, whatever. I imagine the treatment's going to vary through each animal possibly. Are the cabinets available or the chemicals?

MR. GAINES: It is -- the requirements that are in there you could use the same anti-microbial treatment for a variety of species. There's no requirement saying you must use a different one because it's a little better suited to the microbial profiles of that other species so you could use the same ones. If you are slaughtering multiple species there may be some practical difficulties with accommodating whatever equipment you have to the different species. If you have some specific problems with that I'd appreciate some comments on it so we could address that in the final reg. Can you give me a for instance?

MR. LEIDY: Well, I would say, for instance, with hogs, you sell a lot of parts with the skin on and you wouldn't want to change the color or the texture or consistency of the skin. If you're talking about beef they're already skun. You have different animals, different processes,

and that's what I was wondering if the scientific data's there to handle these different species in the same plant.

MR. GAINES: Well, I believe the data is there to show efficacy against all of these. The -- one concern you mentioned about changing perhaps the color of the skin, I'm not aware that that's a problem with those treatments proposed. If you have some information regarding that I'd appreciate seeing it.

DR. NICKLESON: Thank you, Mr. Billy. I know you're in a hurry to take a break. Nick Nickleson of the Meat Board. Just a couple of quick comments. I plead toward flexibility of application. Considering Mr. Lochner's comment, I agree totally, if we know of an intervention strategy that will reduce pathogens it should be required. To my knowledge, we don't know of one yet that does that across the board. Application early's going to be important. We still need to consider attachment and detachment of microorganisms. The carcasses, pre-evisceration, organic acid rinses we know were good but those are pretty limited now because of zero tolerance. I think in doing efficacy studies they've got to be done on real samples. If I inoculate a sample at ten to the eight E. Coli 015787 I can slam it into the wall and maybe get a two log reduction. So I think they have to be done on those samples. We have to see those four in two thousand positives change to one in two thousand positives before we know something's effective or not. I'm scared of mandatory interventions because I think they can become a crutch for processors that want to cover up shoddy steps in the first part of the process. And if Dell can do why should somebody else be able to take a shortcut. They should be considered as processing aids approved by the agency to become a part of the total process in the HACCP program. Thank you very much.

MR. BILLY: We're going to take a fifteen minute break.

(A brief recess was taken)

MR. BILLY: Can we get started please. Rosemary, your turn.

MS. MUECKLOW: Me?

MR. BILLY: Yes, ma'am.

MS. MUECKLOW: The boss isn't back.

MR. BILLY: Take your time. It's okay. He's here somewhere.

MS. MUECKLOW: I'm coming for him. I don't want to start without him.

MR. BILLY: Okay. I'd like to get back to the discussion. Rosemary, you're next on my list.

MS. MUECKLOW: Mike, when you were talking a little bit ago and you talked about your chicken problem with the mean and the guys who weren't making the mean and the guys who were making the mean you made a seriously flawed statement.

MR. TAYLOR: Just one?

MS. MUECKLOW: Well, I got so obsessed with that one I didn't hear any more.

MR. TAYLOR: Straighten me out, Rosemary.

MS. MUECKLOW: I knew that you would cow tow me for this. And that is that you said something that is absolutely the regulatory fixator issue. And that is, that the guys that are really good -- maybe they got to an incidence of only five percent salmonella and I've forgotten where the mean was -- was it thirty percent and then there's some lot worse than that -- you suggested or inferred that there's always -- there's a good possibility that if we don't do something the five percent guys will slide. I would suggest to you that that's a wrong assumption. That when people have learned to excel -- and I see this all of the time in this industry -- people who have become the cream are so jealous of their position of being the cream that they rarely, rarely slide. They're not the ones you've got to worry about. It's the ones down under the line that you have to worry about bringing up to the mean. You're not going to level back the ones that are really good performers back to the mean. They're going to stay as really good performers. Once a good performer there's an enormous market incentive to remain a good performer. So that would skew that picture a bit.

MR. TAYLOR: This is Mike Taylor. I -- my gut instinct, Rosemary, is to, as a general matter, agree with you. There have been arguments made, particularly at the Friday meeting we had on performance standards, that a concern that expressed by some industry participants in these discussions that we need to be careful in establishing performance standards with respect to finished product because then, again, they come in from some industry -- you know -- commentors that will create a disincentive to maintain process control. People will be overly focused on the -- on that performance standard and lose sight of process control. I don't want that. We don't think -- I agree with you that the superior performers have many incentives to perform in a superior way and I think, as a general rule, I agree with you but that's a concern that's been raised and I guess what

I was trying to express was taking off on Patrick Boyle's hypothetical, I think he used the word involving -- you know -- a plant that's achieving some target -- finished -- you know -- product standard without -- and being able to allow a two log growth. Why not allow a two log growth in the chilling process as opposed to a presumably attainable one log if you're meeting the finished product standard. Well, I mean that's his hypothetical. I don't know how realistic it is that plants would let it backslide but we're grappling with the dilemma between the relationship between the rigor of the finished products standard and the incentives that exist for people to observe the state of the art in how they produce their product. We want to maintain incentives. We don't want to undermine incentives to perform at the state of the art -- you know -- in the plant.

MS. MUECKLOW: Well, I understand that you have to look at the averages. That's is an important part from a regulator's point of view but I would suggest to you, you have a lot less problem or lot less concern with the good performers sliding than you do with bringing the poor performers up to the average level.

MR. TAYLOR: I agree with that.

MS. MUECKLOW: The second point I wanted to make is that when we talk about the issues before us right now there's something very different between an intervention and a kill step and indeed we have a lot of kill steps that have been developed at great cost and great expense and great workability to assure safe food but the interventions we're talking about, as good as they are, are not kill steps in the system unless somebody can explain to me otherwise and, therefore, I think their status from the regulatory point of view is very different than mandating the absoluteness of a kill step. When we cook roast beef and we want it to be nice and rare and pink in the middle we better live with those time temperatures that have proven that the system works and that is very, very important. But it's very different from dealing with raw products and our efforts to reduce pathogenic microorganisms to the absolute minimum. Those are two different things and we should never mix them up.

MR. TAYLOR: I agree.

MR. BILLY: Ken.

MR. MAY: Ken May, National Broiler Council. First, I'd like to thank Rosemary. Somebody finally defended the chicken people. And we appreciate it. We don't usually have any help. Even our worst

plants are good. I've told the regulatory people this before but I think it bears repeating. Somehow I think we've gotten the idea that all of our problems occur in the plant and that we get these contaminants on the carcass in the plant. I don't know anything about processing of red meat. Perhaps that's where most of them get there. I really don't know but in the case of chickens and I won't propose to speak for Joe Pocius but I know the literature says the same as the turkeys, most of these pathogens come in already on the skin of the birds. We're not getting most of them on there in the plant. As a matter of fact, we're taking off pathogens normally in our process and that's been shown in many studies. We like anti-microbials. We think they should be allowed. Certainly if it were my preference I'd go with the people who are saying it ought to be a part of a HACCP program and you'd use them or not as you saw fit if you reached the hypothetical goal that we're all reaching for. In fact, we don't understand in the poultry industry why you would not allow more than one if you want to use it and we don't understand why it would have to be limited to pre-chiller. Why not further back up the line if we wanted to use it. Use it anywhere if we're going to be reducing pathogens. That's our goal so why limit it to one and why limit it to one place? Why not post-chill or in the chiller or wherever you want to use it? We also do not understand why you would limit the use to something that would cause one log reduction if consistently you got half log or some other measure and you wanted to use several of those, why not. And I guess that pretty much sums up the Broiler Council's position on this.

I will tell you, Mr. Taylor, that there is a problem that's not generally recognized. It was alluded to by their own -- -- people today. We find that we have a variable microbial load on these birds that come in from the field and I can tell you from almost twenty years of experience with a large poultry company even though we could cite you averages that sounded really good sometimes for reasons we have absolutely no idea the salmonella incidence, for example, go up in a plant and might be up for several weeks or even several months when we have not changed a thing in our operation or how we're growing the chickens or anything else. And it would go away and we'd get back down to our usual good results and I think when you -- whatever you pick as a standard when you get into it you're going to find that that's going to happen sometimes and the agency's going to have to wrestle with what do you do when you have violated a critical control point or

a finished product standard if you have a finished product standard when nobody knows how to get out of that situation.

MR. BILLY: Jerry?

MR. LEISING: Jerry Leising with Cargill Excell. I thought it was important that we comment on the steam cabinet work that we're working on with fertile scandia. Someone maybe earlier mentioned it. This is a method of treating a complete beef carcass. It's a three step process where we do water the surface of the carcass. This is all happening after the final wash where we're dewatering the surface of the carcass and passing the carcass on a continuous chain through a pressurized cabinet and then quenching or stopping the steam treatment with a cold water rinse. The work so far -- we have this installed in one of our plants and we're in the testing stage. Laboratory work showed one to two log reductions and our analysis right now is showing one to two log reduction in the plant on total plate count on coliforms and E. Coli. So we're very optimistic at this point and this test will probably go on for another sixty days so we'll probably be able to get a little more report in sixty days so we're very preliminary right now but we have made progress. Fertile scandia has developed a cabinet system for both small processes as well which would be more of a batch process as well as a continuous process. So it may have a fit as an intervention strategy in some of the operations in the future.

MR. BILLY: Richard?

MR. BECKWITH: Richard Beckwith, small processor from New York State. We've been using in our small plant citric acid for about four to five months. We do not have a moving line. When we first initiated this there was complaints from the employees of their hands burning and so on. I just want to be totally assured that this has been looked into. In other words, there's not a long term effect -- you know -- twenty years down the road that we have -- you know -- people that -- you know -- all of a sudden their skin's coming off their bones. I guess my other point too is this. You know -- we've talked about -- you know -- the treatments and so on but we deliver to some of the worst areas in the world. I mean basically right in the pits of New York City in Roxbury and so on. Now we can do everything humanly possible as far as cooling and as far as anti-microbial loads and so but the minute the product leaves the plant, quite frankly, and I'm sure that there are a lot of you here that have seen it, basically when it

goes in it goes on the floor of some cooler and so on. So I guess what I'm saying is here we're all kind of in a fish bowl, being the USDA and also us meat packers. I think we have to take this one step further. You know -- we're talking about logs and so on but ultimately -- ultimately when the product leaves the plant we have to have a little bit more assurance that what we do in reducing all these loads down and so on, it's all for not if we don't have some kind of safety net to the ultimate consumer. Thank you.

MR. BILLY: Response with regard to the citric acid question.

MR. GAINES: Bill Gaines with USDA. There are no reports of any long term negative health effects associated with citric acid or lactic acid or acidic for that matter at the levels of use that have been proposed in the regulation. Those acids have been used in a large variety of food products and they're generally recognized as safe at the levels proposed in the reg. The second part of your question, I don't know if it needs particular answer, but we do recognize that any positive effects we get from the use of anti-microbial treatments on the slaughter floor could be negated if product is not handled properly from that point on.

MR. TAYLOR: Just briefly to reiterate a point we made this morning and we made in the proposal in February. We need to address the issue of some other -- is there a need for standards governing basic -- you know -- issues like cooling during transport because you're -- we agree completely with your observation and that's a project that we're engaged on right now. We're anticipating putting something in the Federal Register to begin the public process that might lead towards some standard setting. We're working with FDA on it and it's a very critical issue.

MR. ALLEN: Dell Allen, Excell. Just on that, we released a trailer and been running it all summer doing that very thing. We'd be glad to share data with you.

MR. TAYLOR: We would appreciate that, Dell.

MR. BILLY: Angie?

MS. SIEMENS: Angie Siemens, Oscar Mayer. Going back to your three options that you have available I have a couple of concerns on the same option that you're talking about specific decreases. There are a lot of the baselines that you've not completed yet and if you stay with a ninety day implementation that puts several people at a disadvantage not knowing if they are producing under the baseline because the

baseline has not been completed such that -- you know -- do we go ahead and make efforts to put anti-microbial treatment process in when, in fact, we wouldn't have to knowing that we might be under the baseline so I have just some timing questions with the second option right now on those things that are not finished on baselines.

MR. TAYLOR: That's a very good question. If we go that route we would have to figure out how to integrate that with what -- you know -- where we are in terms of establishing baselines so I mean we would have to do that.

MR. BILLY: Bill?

MR. DUBBERT: Yes. Bill Dubbert representing the National Pork Producers. First of all, a report on Beth Lochner. As far as I know she's still waiting. We're concerned -- we have some of our trading partners still at the table but many that we export to are not at the table and you go through the comments -- many of the countries that we export to are very anti anti-microbials and I'm not sure I'm hearing all that much support for some of the options that are listed here. Of course, the proposal said, hey, this can be handled very simply. You just turn off the spigot. But talking to packers that's not a very good option. A lot of times part of carcasses are exported and parts are not and I guess I just bring this up because I think trading is going to be more and more an issue with all species in years to come and this is a little more support for how we're going to handle this. Thank you.

MS. STOLFA: Pat Stolfa, FSIS. I neglected to mention that area of the comments when I was summarizing where we were on the proposal and we certainly do know that it is a concern. I'm hopeful that some of the work that's going on now with what seemed to be the more generally acceptable treatments like different uses of water, including steam vac or other -- even the steam pasteurization process that Jerry talked about -- that those kinds of treatments may have more widespread acceptability than treatments that add compounds to accomplish a anti-microbial effect.

MR. BILLY: We also are -- have a discussion on the 29th, on Friday, where we're going to come back and visit that from the perspective -- trade perspective so -- you know --

Joe?

MR. POCIUS: Joe Pocius with the National Turkey Federation. Speaking for NTF I'd say that Ken May fairly well summarized where we are as well. I want to go back. He did bring up one point that was

brought up two weeks ago in our discussions and that is what happens during certain times of the year when numbers spike. We don't really know why or how or we don't know what to do about it. And then I use the term trending at that time. Maybe it was the wrong word to use but I'm going to use it again because we all can relate to it. That is a changing or moving of the national average on a monthly basis and we're talking about baselines here and two weeks ago we talked about other national average will be one number and that's what we're going to measure against but that number moves each month and it's still the national average and that's what you got to keep into account when you're looking at the numbers or what the processes within a plant are doing -- you know -- how efficacious are they. Well, you have to look against what the national average is at that time. To do otherwise just ignores a lot of the variabilities that we're faced with.

The other thing that I wanted to talk about was a general issue of efficacy for interventions. You've heard some discussion of it already is well, why should we disclude or not consider interventions that don't reach a one log reduction if there's half a log or three quarters or whatever it is but it's consistent and you line these things up together you can additively worsen it or logistically get a greater reduction and I agree with Karen and with other people around here that that is something that should be considered by the agency. What you don't want to get into is the mode of where FDA is right now on their animal drug side where their efficacious efficacy regulations are precluding entry of drugs on the market and you will preclude interventions on the market here. They're aren't very many to begin with. We're only talking about four that I know of and one maybe chlorine dioxide which may or may not actually be used. I understand a lot of people that are testing it are moving away from it. So those are things that need to be considered.

Now, I've heard the counter argument to that is you got to know how good these things work before you allow them to be used in the plant. I mean for goodness sake you got to have some assurance of reduction. And I meant to bring in but I couldn't find it -- it was a Harvard Business Review article from the 80's and it reviewed the drugs on the market. Efficacy requirements were placed into the regulations in the early 70's and what it did was look at drugs before that time and after that time and it measured were there more efficacious drugs afterward and did -- were there more of them and

did they work better than before. What they found out what was no. That just wasn't the case. It just cost more. Before the efficacy requirement the drugs were put on the market and those that did not work were not prescribed. They fell off. The ones that were left didn't work any less better than the ones that were there after the requirement or the testing requirements. I mean the same thing will happen here but even more efficiently, I should think. No plant is going to invest to an intervention that does them no good.

MR. TAYLOR: Let me just make a comment on that, Joe. I can't resist the temptation.

MR. POCIUS: I'm sure.

MR. TAYLOR: In contrast to the Food and Drug Administration which clings to its efficacy standard, I mean we are moving in the direction that has us much less involved in approval of interventions. That's what HACCP is all about. Your proposition about the drug approval process -- it's a highly controversial proposition. You've advanced and did this very substantial argument that's made on the other side with -- you know -- all kinds of evidence martialed as well. In our case, it seems pretty clear that for food safety in meat and poultry plants in a HACCP environment we can move away from the kind of reliance that's currently placed on FSIS prior approval of interventions. That works when we've got appropriate performance standards and we've got a framework for process control because that does again -- the whole philosophy is to put more decision making in the hands of the companies. So -- -- philosophically agree. We're not so sure on drug approval.

MR. POCIUS: That's one of the reasons that I bring it up that the directive that was recently put out on interventions and this whole R&D thing and how do you get a new approval, that may seem like you're moving away from the old way of doing things but in reality it's putting up a few more barriers and then I'd submit that the steam vac cabinet that's been discussed is a good example. When you have a lot of evidence that this works the requirement's being made that it now be field tested and that is just like what CVM does. To be field tested with pathogenic innoculums which is not a healthy thing to do in the processing environment. So --

MR. TAYLOR: I mean we are in the transition on that and we've got a ways to go and I absolutely recognize that. And any specific suggestions, whether it's specific cases or generic or that you've got

for changing the way we do that business we'd invite.

MR. BILLY: Caroline?

MS. DEWAAL: We've now heard from both the National Broiler Council and the National Turkey Federation saying that a large part of the problem is that the products they are getting into their plants are contaminated and therefore they're not going to be able to control it. I can't comment on that but I think that the Department needs to look at the studies which document that a significant amount of cross-contamination of poultry carcasses occurs during the emersion chilling of those carcasses. For example, a 1979 study in the Journal of Food Protection found that eighty percent of the carcasses were cross-contaminated -- cross-contaminated when no chlorine was added to the chill water and when chlorine was added the cross-contamination rates went from fifty eight percent to eight percent. In another study in Poultry Science, thirty percent of flocks of birds were positive for salmonella before emersion chilling while ninety five percent tested positive after chilling. There's another study in the Journal of Food Protection showing that only three to five percent of the broilers coming to the processing plant were positive for salmonella whereas thirty six percent of the broilers leaving the plant were salmonella positive. And, again, another Journal of Food Protection showed fourteen percent of the broilers entering the chiller were salmonella positive while nearly thirty seven percent of the birds leaving the chiller were salmonella positive indicating that emersion chilling is a source of cross-contamination. These are just a few of the studies. There are more that I could cite. I'm not going to spend the time here. I will give the research findings to the agency for their records. However, I think the issue raised here is certainly -- I mean as I stated two weeks ago, I think that the industries have a duty to control the contamination rates in their incoming process that is part of what I see as a HACCP system and a farm to table system for food protection. But you also need to look at the cross-contamination occurring as part of their processing.

MR. MAY: Caroline, again, I now direct your attention to some more results and you might want to talk with Mr. James with the Department about chlorinated chillers versus non-chlorinated chillers and I've asked Steve Pratt to get ready to send you some articles to show that if you properly chlorinate chillers you do not get cross-contamination. And I would also direct your attention to a couple of

recent articles on turkeys that was in -- what -- Food Science, Joe?

MR. POCIUS: Right.

MR. MAY: That found that the biggest predictor of how much salmonella you're going to have in the carcass coming out of the plant was how much was on it when it came in from the field. We're not using that as an excuse saying we're not going to do anything about it. We're doing everything we know how to do and going to continue to do that and that's why we like anti-microbials and we don't deliberately go in there and brush -- you know -- bacteria on anything. We're trying to get it off all the way through. But it is a fact that we don't know how to prevent it because these birds are grown on farms. They're not grown in some sterile environment. And we don't know how to get rid of all these organisms on the farm.

MR. POCIUS: Further, I don't think that what we said that we couldn't control it. I mean if we did nothing at all then I'd have to agree with you but there are things that are done for product coming in in transportation and all that and we've talked about stress in transportation and how we try to minimize that and the holding and all of that and there's additional things that we're looking at right now with Bonnie Fontaine in the production side. It's not a hands up, we don't know what to do. And we are working at that, Caroline, and I think it's taken out of context to suggest that -- you know -- otherwise.

MR. GAINES: Bill Gaines, USDA. I would appreciate, however, copies of all those articles you mentioned. There may have been one there that I don't think I have on file.

What Ken and Joe are saying, however, is true in that the largest indicator of the final bacteriological profile of poultry is what comes into the plant. The studies that have been conducted do show that at the end of each major step of poultry processing the poultry are cleaner than in the previous step. The chiller historically was a problem point in that actually the poultry was cleaner in terms of bacterial numbers coming out of the chiller but it did provide an opportunity for cross-contamination. A couple of good studies done in recent years show that with chlorine added to the chillers that is substantially controlled.

MR. BILLY: Yeah, Jim?

MR. ELFSTRUM: Jim Elfstrum. I think I can add some clarity to this issue. We have done a lot of testing, as I said earlier, in poultry

plants and we need to focus more on most probable number analyses rather than incidence rates. We're doing that in our testing and it turns out that in terms of our test methodology it's like everything else we prove it. We're down to lower and lower numbers in terms of indicating the positive for that particular sample. And we're looking at numbers right now for salmonella presence on a carcass of eight or under ten salmonella per carcass so a one log reduction is illumination on that particular carcass and we -- and if you do an incidence rate analysis you're going to find positives but the numbers are very, very low so everything the industry can do to reduce those numbers is going to help in a great manner in terms of reducing the incidence level and reducing the public health threat that they may present. So the numbers are low even the incidence rates may be high and that's clear to us right now.

A couple of other issues. In our testing we -- I mentioned fifteen thousand samples. Those are fifteen thousand samples from commercial operations. These are not laboratory studies. So these are real. In terms of disposal, that issue's come up vis a vis TSP. They have poultry plants that are not operating with TSP. This is not an issue in terms of their operations. They're able to handle the TSP issue vis a vis the disposal and release. It's not an issue. Thank you very much.

MR. BILLY: Caroline?

MR. MAY: Jim -- Jim -- those eight that you're talking about came off of two thousand square centimeters of carcass area too.

MR. ELFSTRUM: Correct.

MR. MAY: You're checking the whole carcass -- entire carcass.

MR. ELFSTRUM: Exactly.

MR. COOK: I don't question the validity of the studies but I think it's absolutely imperative to understand the protocol in which those results were placed. It's important to understand, number one, the level of free chlorine in the chiller system; number two, the dwell time that was associated with those birds. Previously, we had done a lot of work with turkeys indicating that as you increase the amount of free chlorine in the chill water and you have a sufficient dwell time there's a significant reduction in salmonella in those birds. In fact, the salmonella load of turkeys chilled that way are significantly lower than those dry chilled. For years the European colleagues have touted the value of dry chilling and our experience is that dry chilled poultry

has significantly higher loads of salmonella than those subjected to good efficacy spin chilling.

MR. BILLY: Okay. I'm going to try to wrap this up. The paper identified two or three options in terms of the current thinking. I just wondered if anyone looking back at closing this discussion cared to provide any further comment on the specific options that were there. A number of people already have, I understand. I wanted to provide a last opportunity for anyone wishing to comment on those particular items.

Okay, Len?

MR. HUSKEY: Len Huskey, Swift and Company. If in fact we move toward one or some combination of the ideas that were suggested by Nick and Bruce it would seem that the issue of interventions might also be viewed in the same light as the time and temperature issue so -- and that also falls in line with the idea of moving toward performance standards which we've heard a lot throughout these discussions. Thank you.

MR. BILLY: Okay. Anyone else? No. Okay. We can move on then to the last agenda item for today which is the sanitation standard operating procedures.

Again, I'm going to have Pat just very briefly summarize the paper and the current thinking.

MS. STOLFA: Again, I hope you've had an opportunity to look over the issue paper on the sanitation standard operating procedures and what our current thinking is.

As you recall, the objective of this part of the proposal was dual initially to clarify that companies were responsible for daily maintenance of good sanitation and also to focus both plant management and FSIS attention on the issues -- the sanitation issues that relate to the possibility of direct product contamination. The comments were largely supportive of the concept of sanitation SOP's but probably as we've heard in a number of other areas quite concerned about what we might really mean -- what would be the details and so in a number of instances the comments were in the direction of seeking more detailed information. Is FSIS going to put out any guidelines, are there going to be any model SOP's, how is enforcement going to work? And so our thinking has focused on those practical issues and indeed we feel we can be quite responsive to the desire for additional guidance material to further clarify what our thinking is and

we've attempted in the other portions of this paper to lay out what the key points are.

This is one of those areas that it seems to me that most people's concerns are really extremely practical and since much of the practical work in this area has largely been directed in inspection operations I'm hoping that Bill Smith will once again provide the answers to all the questions that I don't know the answers to.

MR. BILLY: Jim?

MR. HODGES: Just a question to start with. Will pre-op sanitation be conducted in roughly the same manner as it is today with SOP's in a plant?

MR. SMITH: SOP's will be verified through two ways. One would be through a record verification. That's one way of doing it -- reviewing what the plant has said they're going to do based on their program. And then two is hands on and so -- a hands on check -- and we are looking at how we can adopt our existing methodology, meaning a pre-op in both the PBIS system and in the slaughter environment how that could be adopted to a hands on verification approach. So we are looking at that right now as does that help to find a sampling scheme, how much do you look at on a hands on approach or direct observation approach to make that determination. Included in that would be if a plant is using microbiological monitoring criteria as a pass/fail and how that factors into their plan and how that would be considered in that process also. So as it exists today we would still be doing a hands on and we could use it as a guidance -- what we're doing in our pre-op environment for sample selection but that's about what we'd be using it for.

MR. HODGES: Will the SOP's then become the standard that both the inspector and the plant operate by? If they're not and we conduct -- the inspector basically second guesses the plant we're no better off with SOP's than we are under the current system.

MR. SMITH: The answer to that is yes. The SOP's are to meet the regulatory requirements for sanitation that's defined in the rest of 308 and the comparable poultry section and so that would be the standard that the inspector go by. We would expect -- what's important in that is that the plant identifies when things are going wrong and initiates the corrective action and preventive action. That's really what we want to see that that's identified and that's addressed and so really the inspector will be looking for that.

MR. HODGES: Yeah. Just one follow up and then I'll yield the mike. But let's assume a plant has a standard operating procedure in terms of verifying that sanitation was done in a proper manner -- a combination of some kind of visual scoring system and microbiological swabs or monitoring of equipment and they plot that on some kind of trim line dot and basically score their operation. If those scores are within the SOP's and everything looks to be fine is that what the inspector's going to use or is he going to go out and use the white rug to say that -- you know -- I don't think this system's working cause my eyes are different than your's?

MR. SMITH: Again, it depends on what we see. Okay. We focus this on direct product contamination. We ought to both be able to recognize direct product contamination.

MR. HODGES: Then that's a plus. That's a big plus.

MR. SMITH: And that's -- so in that situation absence of direct product contamination and then that scoring system I think that would be criteria to make a decision whether SOP's working or not.

MR. COOK: Follow up question, Bill. You alluded to the fact that everyone should be able to recognize direct product contamination. Past experience with the decision tree at ISG, I think there's a lot of real problems out in the field where the people could really say it's a likelihood to product adulterated or not. I think -- you know -- although we may be seeing the same things the way that the decision tree is being used is absolutely critical in this area. I'm not as confident as you are that we can both come to the same decision whether the product is adulterated or not. Number two, if the inspector does deem the product adulterated per se, is there an official appeals route to that decision? Is there going to be an appeals system that will funnel through Washington or some other decentralized location maybe that one can go? Is there due process being afforded?

MR. SMITH: Let me go back. We are going to reiterate and spend the time on the direct product contamination or high probability direct product contamination. I mean if we have things in the grinder, let's say, there's no filings in the grinder then we've got meat going up the auger, we've got a high probability it's going to end up in that -- it's going to be in that grinder and then we'd have contamination. So -- but we will be emphasizing with our people that it is the direct product contamination and direct production contamination will not include fat under the sink, or fat on the pedal, or blot clot on the wall, and then I

think we can emphasize and I think we can teach that.

MR. COOK: What about condensation falling on a shopping cart?

MR. SMITH: Again -- you know -- I'm not going to say -- I can't say about each and every situation with you.

MS. MUECKLOW: The popular ones.

MR. SMITH: I understand that and we understand that it's our responsibility. I mean we can go through several scenarios -- if it's dropping on a shipping container that's wax coated and product's impermeably packed and there's not a high probability of direct product contamination that's one thing. If we've got product in -- -- beans with no covering and it's dripping right on the product that's another thing and so I think we all can sit here and determine what's the direct product contamination situation is there and we are going to spend significant time in our training to re-emphasize that that is what our focus is because you can see our enforcement action is going to be such that on a direct product contamination is much more serious than in the past where we just retain the piece of equipment and get it washed and we're back in operation again.

MR. MAY: Mr. Billy, I've got to go but I share the -- the poultry industry shares the same concerns you've heard already. Most of us went through a long period of the Department adapting when we first took over the sanitary inspections of our own photo process plants where we make cooked products. That works real well now, very seldom a problem. But I can tell you, you're going to go through the same thing again and we're the guys that hurt when that happens and we're not always going to agree and I think you need to do a lot of training of your inspectors on exactly what they're supposed to do and what our obligations are and we don't need to be second guessed every day.

MR. TAYLOR: Let me just make an observation in response to both -- this is Mike Taylor -- in response to Jim and Ken. I think the paper that we've handed out makes it very clear what our objective is and the kind of change we want to bring about in the practical reality of what happens in plants through a sanitation SOP. We do envision the sanitation SOP as Bill as said and as Pat has said focusing on those sort of current good sanitary practices that are necessary to prevent direct product contamination. And we want to focus our efforts on in conducting our inspections under the sanitation SOP or with that as a tool is whether the plant has got an SOP that's focused on that, is

carrying it out on a daily basis, and has been successful in preventing any sanitary conditions that pose a risk of direct product contamination. We know that we need in order to make use of our resources and do the sanitation job better as it relates to food safety, we have to focus our efforts just as we're increasing the responsibility that we will place on plants to focus their interests on those core -- you know -- sanitary practices that relate most directly to the risk of product contamination. So we know that we're at a shift. We're bringing about a change among our employees as well as perhaps in some plants on how we focus our efforts and the whole idea is focus our efforts on the matters that are of greatest concern from a food safety standpoint. That ought to be the daily focus of sanitation inspection by our inspectors. It is not to say that there aren't sanitation concerns that you care about but they ought to be dealt with in a way that reflects the level of seriousness with respect to the likelihood of direct product contamination. And we ought to be focusing on inspectors and those activities that do relate most directly to food safety and product contamination. We know it's a shift but it's a shift to the direction that is better focused, I think, for all of us.

MR. BILLY: Okay. Angie?

MS. SIEMENS: Yeah. Angie Siemens with Oscar Mayer. I have a couple of concerns about what you just said. Two weeks ago when we were talking about the regulatory change and about the possibility of some regulations being changed it was mentioned that only six percent of the regulations would be deleted and seventy percent would be modified in some form. My contention is if you leave 308 and 318 the way it is you don't adjust the sanitation handbook. You're not going to get to what you are describing to us because those guidelines are very specific. They don't always focus on just direct product contamination and I think you have a real timing problem in terms of changing those regulations in the handbook with the ninety day implementation as you've prescribed in the timing of SOP's being effective and training your inspectors to accommodate that change in philosophy. I see a real timing issue on that occurring in concern with -- you know -- taking the changes with the current regulations as well as training the inspectors.

MR. SMITH: Well, I have a little misunderstanding about that but -- because we can train our inspectors -- again, the focus on

direct production contamination -- but that sort of things like slope of the floor to the drain or things like how high the curbing is on the outside or cutting the weeds, if there is not a direct product contamination situation there then that will not be -- that is not a failure of the SOP. Now, again, we still -- again, we need to address sanitation situations, whether you're doing it another way that could potentially in the long run lead to a problem, but, again, that will not be written up as a failure of the SOP or official control action taken because the curbing is four inches instead of six inches. So while those requirements -- and there is a process of looking at them and seeing they are or they're not necessary or need to modified -- we can still teach our people. Going back to what Mr. Taylor said, such as what is of direct health significance that's occurring at that time and if we teach them that I don't really see how that other is going to influence what they do.

MS. SIEMENS: I guess my only response to that is I hope you can get the training done in the ninety days. We have some concerns that that will be possible or an inspector by inspector basis in the field.

MR. TAYLOR: Let me just say in the spirit of conveying current thinking, we will be looking at that ninety day time frame for sanitation SOP's in light of our training need and what we're evaluating whether that is enough time. I mean we want to be sure we've accomplished the training and so that's under consideration.

MR. BILLY: Jim?

MR. LOCHNER: Lochner, IBP. On the training aspect and a comment on the red meat slaughter pre-op -- through great efforts, and I will say they were great efforts, particularly by Bill Smith, the problem isn't the training. The problem is we have tremendous amount of filters going on giving direction on what the policies are going to be and by the time the filters, meaning going through somebody's ears back through the mouth, the direction has changed and we get into what is supposed to be direct product contamination and what we end up with is if this happens and that happens it's a direct potential threat. It may only happen once in a million years but it does exist and therefore there's regulatory action taken. And that is, we can talk about training but we got to talk about execution. The breakdown isn't in the training. The breakdown's in the execution.

And the comment on the red meat slaughter pre-op -- have had a number of circuit supervisors say the plants are remarkably cleaner

and they are tremendously at pre-op. However, I don't believe that the product output from a microbial standpoint has changed one bit because we're focusing on things on particularly beef slaughter plants that are going to see a hide in the next five minutes and they're -- essentially all effort was wasted and that doesn't mean I'm advocating not cleaning the plant. I'm saying that the focus of attention was wrong to get the output and consequently we've gone through a lot of turmoil and we have added cost and I'm not against adding cost if there's incremental gain but I do not believe in this case that the cost for the increased pre-op sanitation resulted in an incremental gain.

MR. SMITH: We always do learn from such experience. Let me -- I think what we -- you know -- looking back on the pre-op, the one thing we need to do is -- and I think I'm hearing it loud and clear -- is to make a definite differentiation between direct product and this potential and it's clear enough in that directive. The other thing is how you train is instead of a -- you know -- train this person, this person, this person, that we want to take -- we want to select our trainers because, as I said before, an important part of the training is this culture shift. It has to get people focused on this direct product contamination so we want specialists to be able to deliver that message and then the other part is accountability and we need to get that factored in both at supervision and inspection and we'll also actively working on that aspect also and so we -- you know -- you always learn from what you do and so those are things that we have greatly tried to improve on with this.

MR. BILLY: Rosemary.

MS. MUECKLOW: In my long life in this industry I've gone through generations of improvements in sanitation programs in meat plants. And as Bill Smith says, they are all learning experiences. I hesitate to invite Food Safety Inspection Service to be more prescriptive than they have a pension for doing so in all sorts of areas that I'd rather they not be prescriptive in. That I'd like to have some sort of feel for what Bill Smith thinks an SOP for a kill floor -- a moderate size kill floor and a moderate size processing plant looks like. I'd just like to know the document looks like. And, again, I want that document to be one size fits all and it's not because it's not the way the industry is made. But I think it would become a lot clearer maybe to some people around this table although maybe they know what they should look like, but certainly to a lot of the people I didn't

bring with me today, if they had something that they figured was this is what your expectation is for an SOP. I haven't seen anything like that yet. It could be like the sanitation check off list. I don't think that's what you've got in mind for kill plant. It could be like the PBIS ISG Guide. I don't think that's what you have in mind. So you have something in mind.

MR. SMITH: Again, we will be sharing guidelines for what we have in mind and also we have a model that we can make -- we will make available for what we have in mind.

MS. MUECKLOW: Can we see it this week?

MR. GAINES: We have drafts of that. I don't -- I think I'd like to confer with Bill Smith first to see whether or not we think it's at the point where it would be useful to share it with you. Can we answer that tomorrow?

MS. MUECKLOW: You're on the night shift tonight?

MR. SMITH: But just let me broadly here because it's addressed here and we want to see in an SOP that the equipment in the facilities are cleaned and sanitary. Extremely important in that is how is that affecting this -- of that clean determined in a pre-op mode, who's going to do it, who's going to be responsible for doing it, and who's going to document that and is corrective and preventive actions when something is wrong going to be put in place and what they may be. In an operational mode we want people to be able to identify direct product contamination either from the environment which would be facilities, equipment, or pests, or from personal personnel working there, either that being a production handling or personal hygiene, and that when direct product contamination from one of those sources is seen that it is addressed by the plant and corrected in a preventive mode and that that is documented and if we get that we'll be -- it's going to go a long way to make us very happy that that -- those are critical elements of SOP and I think our guideline pretty much is built -- that's a simplified version but that's pretty much what our guideline is built off of and our model.

MS. MUECKLOW: Well, again, it would really be helpful to take away from this not some package of oozing jello but something in a nice tangible form that we say to people, okay, this is the kind of thing you're going to develop to fit your particular facilities. But I don't know a plant probably in this entire country that at some time or other didn't get stopped because somebody had some old smelly shoes in

their locker and it cut off the locker room and the locker room was out for sanitation needs that meant the plant didn't operate. There are all of these funny screws around meat plants and -- you know -- I think it would be helpful for us to go away from here with a clear idea of what you guys have in mind as to what an SOP looks like. It's not that we're not capable of devising one but -- and, again, I don't want you to be too prescriptive about it. On the other hand, you and I have got to get along together on this. We'd like to know what the paper looks like.

MR. TAYLOR: Let me see if I can be a little helpful, Rosemary.

MS. MUECKLOW: You better bring them with you tomorrow. Are you?

MR. TAYLOR: No. No. As the paper here indicates we aren't going to prescribe a particular format. We're not going to prescribe what an SOP must be for every plant. We envision the SOP embodying current manufacturing practices -- good sanitary practices, if you will, that are recognized in the industry as appropriate and necessary to address the risk of direct product contamination. We are going to have guidelines and as soon as we have guidelines we think are ready for -- you know -- public consumption -- after we've had our chance to look at them internally we will share them and you will have a chance to react to them and they are guidelines that are meant to give you that real concrete feel for what -- what we have in mind but they're not going to be a prescription and they're not going to be the only way to do it. We'll get them out just as soon as they're ready to get out and you'll have a chance to react.

MS. MUECKLOW: When do you think that's going to be? I mean I still haven't got the big package of other stuff I've got to pay $40.00 to somebody for yet and when am I going to get this next bundle?

MR. TAYLOR: Let us know when you've been through that stack and then maybe by then. I'm not -- we've got a lot of things in the works, Rosemary, and as soon as we have this particular piece in a form and at a point where it makes sense to get it out for people to react to we'll do that just as soon as possible. I just don't -- I can't promise it tomorrow or the next day.

MR. BILLY: Go ahead if you want to answer.

MR. SMITH: I'm just saying I was glad to hear about all the internal -- we have a draft. I think we can get it to a stage we could hand at least guidelines. We welcome your input on -- to you -- by the time you leave.

MS. MUECKLOW: Good.

MR. BILLY: Tom?

MR. DEVINE: I was glad to hear that the plants getting so much more sanitary and commend FSIS for pushing for further improvements. The basis for that is investigation that GAP and STOP are currently conducting with inspectors and we don't have all the affidavits written up and signed yet but I can summarize some of the initial thoughts that we've learned and these are 1995 conditions. We still have a long way to go. Inspectors have described mixtures accumulating on plant floors, including human and animal excrement, blood, grease, machine parts, glass, plastic, wood chips, dust, insecticides, insects and their eggs. It also raised the question with reference to Rosemary's point of what the issues smell of cause the inspectors have told us that needed repairs of employee bathrooms have been avoided until bathrooms repeatedly have all but one toilet blocked up and leaking on to the floor. Employees must wade through sewage to use the toilet and then track the filth out on to the plant floor. The inspectors give an explanation of how this translate into product contamination. They explained that product falls into the soup on the floor and is returned to the line without rinsing as they "continuous daily occurrence" in some facilities. Inspectors have found literally hundreds of pounds of meat and poultry spilled on to the floor at points where food backed up due to accelerated line speeds. And I would hope that the intensified training brings back -- isn't a vehicle to curb their viligence. To illustrate, I'm summarizing some of their statements. Plant managers argue with inspectors to allow "some" contamination because "just a little" won't hurt anyone. Examples include feces, grease, hydraulic oil, maggots, metal, floor residue, and rancid meat. I think it's irrelevant to the points on SOP's for sanitation and it's great that FSIS is encouraging the industry to do even better.

MR. ALLEN: I'd like to make a comment that I would encourage FSIS to consider as we go through this. A longstanding problem with an inspector's definition of a particular problem of say contamination-wise that then goes on to a PDR and then comes in a piece of paper and it ends up somewhere in Washington that's available freedom of information and it says that this product is grossly contaminated when, in fact, when the real truth is known and the particulars are known gross contamination is maybe two to three specs of fat, two or three pieces of hair on the back of a side puller on the kill floor but

never touches product -- you know -- product surface. Where inspectors use definitions that I think are just maybe to put on alert grossly misused in terms of what the actual facts are. And there's been no direction that I'm aware of coming out of FSI administration to codify, if you will, what is gross contamination. It's a big problem and then particularly when those PDR's are used in your system to evaluate how good a plant performs. That's again what I said the last time. We need to move through a system of objectivity to the greatest extent that we can in this deal. I'm going to -- shouldn't even get started on it -- going to use one illustration of this and then I'll retire and resign and get out of here. There were six people on one of our slaughter floors, myself for the Ph.D. in meat science, the other five were all FSIS people, all of them veterinarians at various ranks in the organization and there was a piece of fat at about the palm size of the palm of my hand cut off of a carcass that was going by on the kill line and IA and one of the DVM's there was a debate on whether it was fecal contamination or not and I honestly could not tell. It appeared to me that there were specks like a lead pencil that when I was a kid would point in my hand. That was about what they appeared like. One of the vets couldn't tell. The other two were convinced that it was fecal contamination and we debated that -- this group of people -- for probably about four or five minutes. One of the guys that use to work for me came over and he tapped me on the shoulder and he brought me to the side of the plant and he says, I have never seen so much education debating on what shit is. And to me that typifies what we have gotten into and it typifies the lack of objectivity that we are trying to deal with and so as we go into this whole environment I hope we will keep that thing in mind that we try to make it as objective as possible so that we don't deal in subjectivity, opinion, and -- thank you.

MR. SMITH: I mean I agree that we need to be able to very importantly determine between direct contamination and that we're dealing with a public health hazard. It's just as important that folks know that when it's there that they react to it and so I think that's going to be important also as a challenge to how industry folks to be able to take those actions when they occur and not have to go -- you know -- look for somebody and then we get in a debate whether I would have had something in place or not, I just had to go find the person. So all that is wrapped up. It's a culture change for us. I think it's a

culture change for some folks, not everybody, but for some folks in the industry too and so there's a perspective that I think we're both going to have to adjust to this culture shift on both sides I think.

MR. BILLY: Ed Manning?

DR. MANNING: Ed Manning, National Association of Federal Veterinarians. I agree with every word that Dr. Allen said. The big concern that we have had for many years with FSIS in sanitation and I have been in public health for forty years -- twenty six of which were in the Air Force -- so we look at sanitation SOP's as being a high risk items that should be contained thereon. We've had direct contamination for health problems to human beings. With, correctly so, the idea of Rosemary bringing up the smelly shoes, this has been a priority in the past. Hopefully, not for the future. When Charlie Cook mentioned condensate I thought I'd see some of the FSIS staff going into panic spasms. The mention by Tom Devine of feces on the floor and I would agree with the statement that, again, with Dr. Allen that the underlying definition and causes of statement by various inspectors has to be carefully weighed. But why do we even care whether they say there is excrement on the floor. Every day shit is allowed to be brought in on the hides of the carcasses. You require the people to be in clean clothing, the floor is to be cleaned, etc. to begin with, and then fecally and often times heavily fecally contaminated carcasses are brought in. You then proceed from there after starting out clean with having filthy fecally contaminated knives, gloves, hands, hands of plant employees, especially hands of the FSIS inspectors who are very carefully and lovingly manipulating many areas of the carcass as they inspect it for the rest of the day and in many cases, not cleaned or sanitized -- certainly not sanitized if that could even be done adequately -- it could be in some cases -- but no one cares. Everyone talks and this was our concern when I first saw these because I believe in sanitation SOP's. But they either ignore or lightly mention the prime cause of the contamination which is the animal feces coming directly into the theoretically spotlessly clean slaughter floor. That's the biggest problem and then the second problem are the human hands, both the employees and the inspectors, and I stress those, and that would be veterinarians as well as the inspectors, though the inspectors maybe don't handle much except those that are hung back, and all the things in their hands. And so we would like to see proper emphasis placed where it should be which is

either strongly recommending and/or requiring adequate cleanliness within the technological parameters you can achieve these days with the hides and this fits right in with Dr. McKenzie's statement from New Zealand -- they have very thoroughly found with very good studies that the only really critical control point that does any good at all is having short, clean, dry wool on the sheep. And anything else that's long, wet, and dirty you bring into the plant and the other things you do are essentially irrelevant. Well, the things we're talking about with the general SOP's here are irrelevant in comparison to the relevancy of human hands, knives, saws, and the hide itself. Thank you.

MR. BILLY: Dane?

MR. BERNARD: Thank you. Dane Bernard, National Food Processors Association. May I ask a quick question and based on that answer then I'd like to get back. When you were talking SOP what does the agency right now -- how do you define that acronym? What do you mean by SOP?

MR. SMITH: In this instance sanitary operating procedure.

MR. BERNARD: Thanks, Bill. The point was --

MR. SMITH: Standard. I'm sorry. Standard operating procedure.

MR. BERNARD: It's become, as we've discussed it here, sanitary operating procedure. Standard operating procedures -- you know -- it's just a description of how you're going to do a certain operation. I mentioned two weeks ago that we should be concerned about the language that we use when we're talking HACCP and if we're not talking HACCP we should use different words to describe maybe the same activity. You've used the words verification, preventive actions, corrective actions, all in the context of things which may not be included in a HACCP program. I would ask you to consider very carefully whether we need to substitute different vernacular -- go back to the Thesaurus and see if we can up with some different words because it's important to convey a clean message in terms of HACCP being the target and critical control points being more important than anything else that we do.

Sanitation SOP's, I take a different view than Rosemary. I think if you've got a model document you ought to burn it. I worry that we're getting back into the same mentality of command and control. If you put out a document that says is a proper sanitary operating procedure that the industry is supposed to pattern after that's exactly what's going to happen rather than go out and give general guidance which is

all product contact surfaces must be clean and sanitary, etc., etc. Clean out -- --. The documentation or guidance documents are there. Now you build a program around those and we will look at it and determine whether we think it's okay or not. Sanitation is very, very important but if you get prescriptive about it in terms of putting out a document that's very specific and I know this is controversial that my fear is that we're going to go back saying, okay, here's the pattern, every inspector in the field is going to pick up that pattern, and then everybody gets held to a yardstick which may or may not be appropriate for those establishments. Sanitation in general is not a HACCP critical control point. In our comments we were very specific about that. If there is a specific area which a sanitary procedure is necessary it must be conducted in a certain way to prevent direct product contamination then it may be a critical control point. That operation would be, not the whole sanitary operating program. So what I'm trying to convey here is to separate in terms of what's going into a HACCP program, critical control points from things that are important to do, but not critical control points.

In responding to what Mr. Devine said, if we have plants that are operating under those conditions you do not need SOP's to find out who they are and to put paper over them so that you can get them out of business. You shouldn't put up with that. And I don't think we are. I think that we do have to look at what is described as those contamination and get some agreement about what we're talking about when we're talking about direct contamination. If product is falling into things on the floor put them out of business. Nobody in this room is going to defend that. Thank you.

MR. BILLY: Ron?

MR. PRUCHA: Ron Prucha. Two comments. One is to back up, I think, the comments concerning the focus on direct product contamination. It is very much necessary, I think, from what I've been seeing in my last two to three years of consulting is a -- what I would term a zero tolerance mentality that any finding is written up as a PDR regardless of whether it has product contamination implications or not. Any finding is written up. PDR's are -- come down and, as I think you all are aware, PDR's are the stuff of progressive enforcement and a plant can soon land into a progressive enforcement mode by having -- and I have seen in my experience and travels plants shut down or stopped or delayed starts for things like a couple of hairs on a

knocking box door, a stain in a men's urinal in the men's room, and a small piece of fat in a drain. This is how it is being interpreted at the present time and this is the state of the art for, I think, consumer protection and consumer safety as practiced by a lot of inspectors out there. It has many of these have little or nothing to do with food safety or consumer protection.

The second comment I would make is that for implementation. I personally feel that the agency does not need to reinvent the wheel as far as sanitation SOP's are concerned. Some -- oh, I'm guessing now -- twelve to fifteen years ago the present pre-op system for poultry slaughter was put into effect and this was the random selection and forming of units in the random selection of units for pre-op sanitation. This was by inspection. This was put into effect in red meat last year with varying results at the present time. But I think the system is very good. The structure behind it, the theory behind it is excellent. When the red meat went in there was also a companion directive. I think it's -- I wrote it down -- 11,040.2 dated August 3rd of '94 that allows for PQC system -- a plant to submit a PQC plan. I know PQC's are kind of going -- they're not real popular anymore -- but a plant to submit a PQC to take over the government's role in that -- for pre-op sanitation. I have been in two plants where that system is working with very excellent results and the plants are operating the government system of pre-op sanitation. I would suggest that that PQC system be made mandatory and all plants write up what they are doing for pre-op, for operational sanitation, for employee practices. That is their SOP or whatever you want to call it. But turn them loose and let them run with it because that's the only way that I can think plants will improve over the long and short period as far as being able to control their own destinies. Thank you.

MR. BILLY: Len?

MR. HUSKEY: Yes. Len Huskey. I would like to ask Bill how through the process of training and the cultural change that we can deal with an issue that is often unspoken but yet one that heavily influences the relationship of the establishment or management questions and action by the agency or in the future when we have, as we will I know, issues of dispute resolution and what I'm talking about is retaliation and sometimes it's subtle and sometimes it's not so subtle. But I would hope that's where this process of training and culture change -- that can be surfaced and be removed from the picture

somehow. Thank you.

#5 MR. BILLY: Katie?

MS. HANIGAN: Katie Hanigan with Farmland Foods. Question for Mr. Smith. Do you anticipate your guidelines for SOP's for sanitation to include microbial testing?

MR. SMITH: Again, the guidelines talk about cleaning of equipment and then effectiveness. It does not mandate anything. It suggests these are things that could be done. It really gets into that if those things are going to be used as effectiveness then they be part of the plan so they can be monitored as part of the record keeping but it does not suggest that every plant has to have a micro program, does not suggest everybody has to have a sanitizer, does not suggest that those are things that can be used but is not mandatory. What it does suggest though is that it is very important to identify how that effectiveness, however it's done, is determine how it's checked, how it's recorded, and the corrective and preventive -- and I don't really think that's wrong language to use, corrective and preventive. We have a long, long history of using that, way even past the QC's so I would hate to have to come up with something different than corrective and preventive actions. I don't think that's unique to HACCP. I think it's very important that our people and the industry understand that that's what we're looking for -- a corrective action to deal with the immediate situation and prevention to be put in place to keep that immediate -- to prevent that immediate situation from occurring again. So I don't know if there are other words for those but -- you know -- that's clear, I think, for everybody. And then, again, the guideline talks about being able to recognize those situations operationally that have direct public contamination and what's important again is that somebody is empowered to act on those immediately and correct the situation and document what's been done and also have preventive action. So that's -- and the guideline doesn't get any more specific than that.

MS. HANIGAN: Thank you.

MR. BILLY: Bruce?

DR. TOMPKIN: Yeah. I'm Bruce Tompkin from Armour Swift Eckrich. I guess I'm Dane Bernard's echo that went in one ear I'm going to send back to the other way but words are important. It would be desirable to have different words so that they aren't confused with HACCP because we're going through a significant change at this point

relative to HACCP. I'm glad to see in both the proposal as well as in your current position that sanitation is a prerequisite program. That's very important at this point. It's one of many prerequisite programs. If, in fact, you do come out with a guideline or model or whatever it might be would it be possible to break it into two portions perhaps. One would define what the minimum requirements are and the proposal -- this is very clear, I think, in terms of what the establishment must do to comply with this proposed rule and then proceeds to discuss things that could be done or might be done and to throw those all together would create expectations that may be unreal and so for clarity as we move toward requirement for written sanitation SOP's this guidance must come across very clearly as to what's the minimum.

MR. SMITH: In our draft guideline we are making that distinction between what is -- what would be considered minimally -- you'd have to have as opposed to what is nice to have. So if we can make that clear we will. But that concept is in there.

MR. BILLY: Julie?

MS. LAHR: Julie Lahr, Excell. I'd just like to make a couple of points here. I worked in this business as a microbiologist for about eleven years and have worked with clean up companies, have worked through standard operating procedures, and we use them now. But what we use them for are guidelines on which we provide a clean plant in the morning. The SOP's are not considered CCP's where you have direct control over the microbiological -- the floras that are present on the equipment and we need to keep in mind that no plant is going to be the same across the board and I work with plants from one end of the country to the other and depending upon their situation, whether they have a lot of hard water, it's difficult to clean, they have build ups on the equipment, it's impossible sometimes to try and put one standard operating procedure or general operating procedure and apply it to all plants. And another issue that I would like to deal with in terms of SOP's or operating procedures in terms of operational sanitation -- right now we work really hard during operations to try and keep things as clean as possible. And at this point right now we have an issue that we don't quite know how to deal with and it's a directive that is issued by your agency that states when the floor temperature goes over fifty degrees that we have to wash everything down on the fabrication floor and I have seen and stood in the background and watched them spread contamination all over the entire floor simply because we have to

wash down and that's one of the things that I wish we could look at in terms of standard operating procedures. What do we do when that fifty degree temperature goes up? We don't want to spread the contamination. Thanks.

MR. BILLY: Caroline.

MS. DEWAAL: Gosh. I -- my initial desire to speak really was to respond to Rosemary Muecklow. I think a lot of people have responded to her. I do want to clarify though that sanitation in plants isn't rocket science. This is not something where I think the agency needs to do a whole lot of hand holding. There should be basic understanding in the industry what good sanitation is and what sanitation SOP's are. Maybe I'm expecting too much but I just can't believe that this isn't fundamental to producing a safe product.

I have -- you know -- we have advanced deficiency notices, we have tons of documentation. Tom Devine gave some of it. I mean I could certainly read from others and what I'd rather do -- I guess I'd rather submit them to the agency and share them with any reporters or other people who would like to know about what unsanitary conditions are present in plants today. The bottom line is there is a long way to go on this issue. And it is just extremely frustrating to me to come to these meetings and hear the industry arguing about such simple concepts -- you know -- the need for good sanitation. If there's a need for new words here maybe we need the term HACCP-like. The interim standards of temperature controls of sanitation are HACCP-like. There are things that are ultimately going to be incorporated into the full blown HACCP plan but they're going on line a little earlier. And then there may be products that you need HACCP plus and there you'll need actually CCP's defined to address specific public health problems like maybe E. Coli 015787 but, I mean, these are not concepts that at least from a consumer's standpoint seem like we should be having to struggle over quite so much.

I also have a clarification for the record. Again, this is responding to something earlier that Rosemary Muecklow said. There was -- there is not -- and I'm making this clarification because I don't want anything to be misused on Capitol Hill coming out of this meeting -- there is no consensus around a new approach to time temperature. The consensus that Rosemary may have thought she was achieving just didn't exist. Consumers aren't on board. Frankly, I don't even quite understand many of the proposals. I'll certainly read up on them I'm

sure. The issue I really have on this is why the hell -- excuse me -- why the heck are we looking at consensus building this late in the game. The Department had a five month comment period of this rule. They had science and tech meetings and public hearings. They had -- I mean some of us are so meeting out on this particular rule it is just ridiculous and suddenly to have Rosemary Muecklow and others coming in and saying we've got to have consensus before we can move forward and you've got to delay the rule, you can't put the rule out. Where were you during the comment period? What about achieving those things during the comment period when that effort should have been going on? I believe the Administration tried to get consensus around issues it considered controversial and that a lot of us participated in that effort. So I just want to be very clear that there is not consensus on the time temperature issues. I'm happy to look at anything. I'm open to consensus generally but at this stage this is late. This proposal is ten years late in our book and we are not at a point where suddenly the industry running in at the end of the game saying we can't move forward because we've got to have consensus. I just don't think that's the right approach. Thank you.

MR. BILLY: Jim?

MR. HODGES: Jim Hodges, American Meat Institute. When Caroline started to talk I thought there was something we could agree on but in the end I guess there's not.

I want to return to the subject at hand right here rather than to address all of the issues that Caroline has brought up. The issue we're talking about is sanitation SOP's. Before, I did indicate I thought there was some agreement. We're not talking about it being a controversial subject. We're not talking about it being unclear about what sanitation is in a plant. I think that becomes relatively clear if you go into a plant day in and day out. What we are talking about and where there is considerable concern is how does the inspector relate to that new regime of the SOP. That's what unclear. It's not the sanitation of the plant. It's how the inspector relates to the new regime. Now, if that is the question that's unclear and that's the question that probably will not be fully resolved until we actually get implementation of sanitation SOP's it's imperative that there be some quick appeals process or dispute mechanism set in place so that we don't have plants that are unduly subjected to harsh regulatory action that has no effect on food safety. It'll happen. We know it will happen. Bill, you and I

have been around that many, many times, and there needs to be with this new program some kind of system set up to clarify when there is a dispute between the government and industry what is the correct action.

MR. TAYLOR: This is Mike Taylor. If I could just respond briefly. We based on the discussions two weeks ago when we talked about inspection under HACCP we are looking hard at the question of what is the appropriate -- you can look at it as an appeals procedure, you can look at it as how do we provide the necessary backup of inspectors. There has to be a way to resolve disputes, particularly in the HACCP environment where there are going to be questions that are different than the questions we've been asking inspectors to resolve historically so that sort of appeals issue certainly is on the agenda and I think could certainly be applied under the right circumstances in the sanitation SOP area as well. We're working on that and we have some ideas.

We also -- again, there's been a lot of focus in meetings we've been having on not only what the new regime might be but how inspectors relate to it as you put it and I think we've had some good discussion of that. We certainly intend in the preamble to the final rules to articulate what our thinking is about that as it has developed and will continue to develop and that needs to be laid out for everybody's purposes. I mean that issue of how we change the cultural environment, not only among our employees but your's, that is something that will evolve over time so we're not claiming that anybody is going to know fully exactly what it's going to be like and what inspectors will be doing five years from now but our best thinking about what we expect the role to be, what we'll be instructing our inspectors to do -- I mean our current thinking will be laid out as fully as possible in the preamble to the proposal and it will be an on-going thing.

MR. BILLY: Bob Biddle.

MR. BIDDLE: We have some brief comments to the question of potential co-existence or overlap between SOP's and for the fully functional HACCP plans. We can quite readily visualize the intent of the proposed rule to use SOP as a transition to a HACCP system. We cannot readily visualize is once sanitation requirements have been translated into HACCP plans why some aspects of SOP need to continue in existence. We believe that under proper HACCP disciplines all the

objectives of sanitation programs for immediate cleaning of equipment, periodic maintenance of the processing environment, and general environmental sanitation that's important to the overall objectives can be addressed and properly structured in HACCP plans. They need not be addressed for a critical control points. But the objectives of sanitary production can be achieved under these plans and we do have a degree of difficulty with the proposal -- the wording at least that comes through in the discussion paper before us today that appears to see a role for co-existence of SOP and operational HACCP plans. We think that this -- and much of the potential dispute here is that has been alluded to today can be resolved within a properly structured HACCP approach to these issues. So I think it is an area that could be further considered. Thank you.

MR. BILLY: Bob Hahn.

MR. HAHN: Bob Hahn, Public Voice. I just wanted to say that as far as the content of the guidelines or the model SOP's that I think they should go considerably beyond clean equipment, including as was mentioned before, hide sanitization and effective hand washing. I also had a question about the proposed standards on fecal contamination for poultry. They don't include ingesta which are included for beef. Also the standards for poultry are finished product standards and I would assume that when the poultry comes out of the chiller that most of the visible contamination has been rinsed off already and I was just wondering why there would be more lax standards for a product with such a high rate of contamination?

MR. GAINES: Bill Gaines, USDA. I'm sorry, why there would be more what standards?

MR. HAHN: Why there would be more lax standards -- lax for chickens -- for poultry than the beef.

MR. GAINES: I see. We have requirement that feces and ingesta be removed from carcasses before they go into the chiller or the cooler. That's livestock and poultry. That's the same standard.

MS. DEWAAL: Isn't one a wash standard and one a trim requirement?

MR. GAINES: We do have for poultry the requirement or the option for reprocessing poultry rather than trimming it if it's on the skin of the bird. That's true.

MR. COOK: Mr. Chairman, I believe this issue is not the subject we were discussing. I fail to see what that has to do with sanitation

that was being discussed at this time.

MR. LOCHNER: I think it is. It's operational sanitation.

MR. COOK: Jim, you're going to include those standard operating procedures?

MR. LOCHNER: Yeah.

MR. COOK: Jim, I think you're pushing the issue a little far than what we're talking about. I think what we were talking about were standard operating procedures for sanitation. What we're alluding to was pre-op sanitation issues.

MR. LOCHNER: Charlie, I beg to differ with you but we're talking about sanitation which includes operational sanitation. Where is this limited to pre-op sanitation?

MR. COOK: I think addressing fecal matter on any carcass of meat is not a sanitation issue as has been past perceived or currently discussed.

MR. BILLY: Dane?

MR. BERNARD: Thanks. Dane Bernard, NFPA. The comment over here was go ahead, straighten this out.

I don't know if we can do that. There was one thing that Caroline and I can agree on. She started out by saying sanitation is not rocket science. It's not. We're trying to make it a bit more difficult than it is. I go back to what I said earlier in terms of language. Bill, maybe we have gone a bit far in other areas in that language may not be a problem. I'm just bringing it up because conceptually we want to move away and provide clear distinction between HACCP and other things that we do and if we can tinker with the language a little bit so be it.

SOP's should be developed, by the way, for every critical control point in a HACCP plan and that serves as a basis for training people who do those functions at those critical control points and in a SOP document maybe we change it there. I don't know. But an SOP to me is just say what it is that needs to be done at a particular point, whether it's -- you know -- a sanitation operation or whatever. But I was trying to give you the idea that we should separate the language anywhere we can. Now, if I look at the paper that was passed out here, open hymnals to the second page if you will. The bottom paragraph here -- failure to have a sanitation SOP. This next few words bothers me a bit -- or to consistently follow it or the presence of unsanitary conditions that could result in product contamination -- product contamination's obviously something we don't want to have -- would

require immediate regulatory action. Thinking about what was said earlier about the lady from IBP, sanitary SOP's are in essence guidelines to achieve a goal. They are not etched in stone as HACCP critical control points are. In response to not following an SOP exactly should be contingent upon what the result of not following it is. If somebody did something equally effective, if it wasn't in the SOP, fine. If you, for example, didn't follow an SOP but you made -- to use a HACCP term -- corrective action that made the situation okay, fine. Even the corrective actions, you're not going to be able to spell out every potential way of fixing something that comes up in a sanitary plan. This was why while it's nice to say give us guidance on what you look for, I think the guidance should be general and it should give us a very plain idea of what needs to be done but that's already in the plan. I didn't want to go against Rosemary who's much more wiser than I on many of these things but to me, if we come out with this what the agency wants, this is an SOP, I see that as boink, here it is, and the industry allows this to happen over and over. Okay, here's what the agency wants us to do, by God, this is all we need, we'll comply with it. What we're trying to do is get away from that mentality both in the industry and in the agency and I see that if we put out some piece of paper like it, if we don't qualify it, if we don't say look guys, this is only a model format what we want you to comply with is here in the general guidance document, clean outer wear, clean surfaces and that sort of thing, and let's not make it overly complicated cause the old story about the duck that's very applicable. If we make sanitation look like, walk like, and quack like a duck, we're going to think it's a duck. And we want HACCP to be the duck. Thank you.

MR. BILLY: Rosemary. I think this may be the final word.

MS. MUECKLOW: Good. It's been a long day. I'm disappointed that we hear from Caroline three hours after we had a very substantial discussion about the carcass cooling requirements that she doesn't like that. I'm sorry we didn't have that input three hours or so ago but fortunately you provided a remedy and that is that the hearing record will be open for thirty days and I'm sure that Caroline can submit her views for the record. I thought it was our better moments today because indeed we were talking about what can be done, is it good science. We were having the realistic discussion that we've not been able to have throughout the comment period and I think we made some real progress to sorting out something that is very important and has

been very contentious during the discussion of this rule.

Contrary to what some folks may think I haven't been asleep under a stone in my garden in Berkeley, California for the last six months or so. In fact, we have been very active as an organization and I have particularly in being concerned and involved and contributory to the rule making process. As several of you in this room know it didn't seem to be responding to what we needed and we're very grateful that Mr. Taylor and Mr. Billy and Secretary Glickman himself provided for this additional opportunity for us to visit and if there's any testament needed to the fact that it has been valuable it has been the last four days of discussion on this issue, three, two weeks ago, and today's discussion and being an old war horse that I am I'm going to be here for two more days this week like a lot of other people in this room and I hope we will continue to have this kind of discussion. I think it is extremely useful and, again, I haven't been asleep.

The final issue that I seem to be having to defend myself on is that we have never thought that sanitation is rocket science. We believe that it is a daily behavioral activity. I don't want anybody to suggest or think that I come to this table or that anybody else around this room doesn't understand just like you get up and have a shower and clean your teeth every morning so you clean your plant every day. And I don't know where Mr. Devine's comments came. I hope that when he publishes them that they will be published and we will find out what those officials with responsibility for enforcing a criminal law did about these terrible conditions that they saw. The kinds of things he characterized are certainly not commonplace in my thirty five years experience in this industry and there are enough inspectors around this table. They know that they wouldn't tolerate any kind of condition such as some people have testified to to Mr. Devine. So we certainly hope that that issue can be clarified and resolved. But I am here to tell you that people that I speak for I know firsthand are running very clean plants and my only request, despite my difference with Mr. Bernard, I think it would be helpful to have one simple little page saying this is the kind of thing that you really ought to have on the shelf and I certainly hope that I can get that despite the fact that it is slightly prescriptive I think it would help in cultural change of how we're all looking at sanitation. A lot of people have a lot of pieces of paper on it. If they need to begin to make changes and I'm sure many of them do it would be nice to know what the piece of paper ought to look like or

the book or however you want to consider it.

Thank you very much for the opportunity here today. It's been one more great experience to write about some day. Thank you.

MR. BILLY: Okay. I'd like to thank everyone. We'll start again tomorrow morning at nine o'clock.

(Whereupon, at 5:52 p.m., the meeting was adjourned.)

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PATHOGEN REDUCTION/HACCP RULE
Name of Hearing

_____
Docket No.

U.S. DEPARTMENT OF AGRICULTURE, Washington, D.C.
Place of Hearing

September 27, 1995
Date of Hearing

We, the undersigned, do hereby certify that the foregoing pages, number 2 through 225, inclusive, are the true, accurate and complete transcript prepared from the reporting by Joshua Connor Cagney, in attendance at the above identified hearings, in accordance with the applicable provisions of the current USDA contract, and have verified the accuracy of the transcript by (1) comparing the typewritten transcript against the reporting and recording accomplished at the hearings and (2) comparing the final proofed typewritten transcript against the reporting or recording accomplished at the hearing.

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