P R O C E E D I N G S

MR. BILLY: If everyone would have their seats I'd like to get started. I'd like to thank everyone for coming. This is the third day of these meetings to have a discussion, a dialogue about major issues that have been identified and associated with the HACCP and pathogen reduction proposal the agency published back on February 3rd. Today's subject area is performance standards in microbial testing.

I want to make a few announcements first and then I'm going to propose a little different format for today that's going to be, I hope, one that will lead to more of a dialogue on the very specific issues.

In terms of the announcements, again, we do have an overflow room. It's 4347. If we're not overcrowded in this room but if anyone has people that otherwise wanted to attend but were worried about space or particularly people here in town we're broadcasting the meeting up into that room. You can observe and hear the activities and anyone's welcome to use that. We also have a caucus room, Room 3831, that's available. There's a sign-up sheet. If anyone wants to meet during a break or the lunch hour you're welcome to do that and just let the people at the desk know.

In terms of the schedule for the day it will be similar to the last two days. We'll go till about nine thirty or so. I'll then call a break for about fifteen to twenty minutes. We'll get started again and go till lunchtime and a similar pattern in the afternoon.

In thinking about today's session where we were starting out and narrow from a general discussion about HACCP or the role of inspectors, even though we got into some fairly specific areas, we're now starting to get more specifically into some of the technical

issues. We have -- if you look at the agenda we have here identified under A and B several specific points in the form of billets. Each of those billets really represent major issues that were raised in the comments -- you know -- concerns that were raised and so here's my suggestion on how I'd like to see -- have this work and we'll see how we do. It's still important that speakers use their table tents with their names on it and use them to identify when they're going to speak and when they do speak to state their name and their affiliation because this is on the record, it's going to be part of the formal record for the rule making. But instead of the sequential process, like I've used the last two days, once we do the introductory -- introduce the -- our current thinking and so forth I'm going to go to this list of billets and start a discussion on each of them and then we're going to have a dialogue so I ask that each of you respect the others. In other words, we need to discipline ourselves in terms of taking turns but if there's a point you want to make about what someone just said please do that. It's going to be dialogue. This is a pretty big group so it's going to be hard to make this work but I'm going to try to make it work for all of us and we'll just have a discussion. You still will need to put your tent up to be recognized back here and then say what you have to say and keep an eye yourselves on who else is waiting to speak and have a sense of the flow of the discussion. We're going to try and see if that will work. There will just be a dialogue about these specific issues that all of us have identified and if it works then we'll just use it. If it doesn't I'll draw back to the past approach.

Are there any questions about that? Okay.

Yes, Rosemary?

MS. MACKLOW: Can I just ask --

MR. BILLY: Sure.

MS. MACKLOW: You're obviously recording all of this and also videoing it or just recording and the video is going to transfer?

MR. BILLY: I think the video's just instant transfer to the best of my knowledge. It's just so that it's available on the LAN system here for the room upstairs or anyone else.

MS. MACKLOW: What's the availability with the tapes or copies?

MR. BILLY: The tapes will be available, I think, about two weeks -- is that right? Who knows? Two weeks.

MR. TAYLOR: Video tapes or transcripts.

MS. MACKLOW: Oh, I understand you're going to transcribe it and have somebody -- I know that's going to take time.

MR. BILLY: Is there a tape of this?

COURT REPORTER: We're taping it.

MR. BILLY: Okay. Let me check into it and I'll get back and tell you because I didn't even know we were doing this. Okay. I'll let you know.

All right. I think Mike, again, wants to kick off today's discussion so, Mike.

MR. TAYLOR: I just will just take one minute here to open up the conversation and then Dr. Morris will talk in some detail about our current thinking. But for those of you who have both read the proposal from February and read this paper -- you know -- it's evident that -- and I think actually listening to the conversation the last two days sort of reflected this as well -- we see microbial

testing to verify achievement of certain performance standards to be an integral part of a HACCP-based system for controlling and reducing harmful bacteria on raw meat and poultry products and we well recognize that this concept is a very significant departure from the traditional regulatory paradigm that we have used to oversee the safety of meat and poultry products but it is one that is designed to harness the science-based process control tools that, again, are embodied in HACCP and to provide an incentive for an improvement of process control by having objective measures of performance against which we can both verify that process control is working in the general sense and also have means for measuring and having accountability for reducing pathogens -- reducing harmful bacteria.

The proposal really put the burden of both verifying process control and measuring reduction of pathogens on a single organism, salmonella. And if you, again, from reading the paper, we've learned a great deal from the comments and from the scientific conferences that we've had. We've had two conferences really that addressed this issue -- the Micro Testing Conference in Philadelphia and the Performance Standards Conference here at Georgetown and I think we've learned a great deal about the role of microbial testing, the way to make good use of it, and the way the performance standards can be built into the system and what we learned at those conferences as well as through written comments is very much reflected in the current thinking that you see in this document. This is thoroughly a work in progress. When we say current thinking we mean this is today's current thinking. We've worked hard to sort of go through a thoughtful process in the agency since the close of the

comment period to arrive at this but we have been very much looking forward to today's session as a way to really -- you know -- have a serious conversation about how we can achieve the objectives of the proposal in this area. And we remain very open to how we achieve these objectives and if there are better ways to achieve the objectives than we've currently arrived at, I mean we welcome that. The idea is achieving the goal. We're not wed to how we do it. But, again, all of us have been looking forward to today's conversation and I particularly -- I just -- I hope Tom's approach to fostering dialogue works because from our standpoint we want to put out these thoughts and Glenn will walk through -- you know -- walk through our current thinking. But what would be most beneficial for us is to have interaction with you -- between you and the agency -- but even more so sort of among folks who have competing points of view because it's really going to be out of that dynamic exchange that I think will get the best insights as to what the pros and cons and shortcomings and advantages of our current thinking are and so, again, we're looking forward to today's conversation and the discussion.

I want to acknowledge, in addition to Dr. Morris who will speak in a moment, the presence of Dr. Maury Potter from CDC who is graciously investing his time up here for these meetings representing CDC and Maury's expertise and familiarity with these issues is well known to everybody and we're happy to have our sister agency at the table today.

With that, if there any just immediate questions, comments, I'd be happy to take them. Otherwise, maybe the best thing to do is let Glenn convey our current thinking. Thank you.

DR. MORRIS: Yesterday I got the honor of conveying current thinking and, again, I would emphasize what Mike says, which is that this is indeed current thinking and in contrast to -- you know -- yesterday where we had answers for at least some things I think in many of the things we'll talk about today this is current thinking and we do have the answers and what I would ask is for your ideas and concepts and your suggestions to specifics as we begin to go through this.

What I would like to do is at least lay some groundwork to give you a feel for what our thoughts were as we put the rule together and, in turn, what our thoughts are at this point in time as we've begun to assimilate the information that's come to us from the various scientific conferences and the comments that have been coming in. When we first started putting the rule together there were sort of two underlying concepts which went into the idea for microbial testing. One was the need for pathogen reduction. The idea that there was an immediate need to reduce the level of pathogens on foods, to deal with the specific public health issue of pathogen reduction. The second concept was the importance of microbial testing and process control. The idea that if you're doing process control to attempt to produce a safer food that you have to do microbial testing; that is an integral part of the process control. In trying to unify these two different concepts we proposed salmonella idea which was in the Federal Register document which was to essentially use a pathogen as a means of moving toward pathogen reduction targets but sort of getting -- you know -- double use for our organism to also use it as a process control indicator -- to do two different things as a single

organism. We identified a target for salmonella. Now identifying targets is always fraught with difficulties but in this case the targets which we identified were in many ways technology-based. What we said was maybe the best way to approach this is to look at the current national average. Now the thing about an average is that if you have an average that means half the people are better and half the people are worse and if we are moving toward pathogen reduction our concept was, well, as a first cut that it would be reasonable to use the national average as our target. The idea was to move the half of the production which was above the target to the target or below the target and, so, again, it appeared to be a reasonable target to set as a starting point for pathogen reduction. The other issue that came up in setting salmonella and plans that went into the current pathogen reduction document was the idea of whether we use a level. In other words, "x" number of CFU per mil or however you worked it out or whether we should use a percent of product. Again, coming at this from a public health standpoint we felt that what we really wanted to look at from a public health standpoint in terms of pathogen reduction was percent of product; that bacteria multiply if they are mishandled and what we really wanted to do was reduce the percent of product that carried the bacteria. Taking broiler chickens -- not to pick on the chicken industry -- but using broiler chickens as an example, the current average is twenty five percent, and so what we wanted to do was to try to bring everyone to that average with the idea that we wanted to reduce the risk that a product containing a pathogen would go into a household, go into a kitchen, go into a restaurant. So those were the ideas. Those were the concept behind

the current proposed reg.

As we went into these meetings there are several things that have emerged from the comments and from the scientific meetings. The Philadelphia meeting strongly emphasized the utility of E. Coli as a process control indicator. That was very clear from Philadelphia. That was very clear from the Georgetown meeting. That is also clear from the comments. And as you will see in the document that we passed out yesterday I think that's where our thinking has moved; that if we're going to do process control that E. Coli -- quantitative E. Coli is probably the best indicator for process control. However, the other thing that emerged, particularly from the Georgetown meetings, was the importance, still, of pathogen reduction. And, so, I think to give you a feel for where our thinking is right at the moment, the idea would be to separate out these functions, to recognize that -- you know -- we were going through a one size fits all at the beginning and trying to get one organism that would -- you know -- provide everything we wanted and that maybe that's not the correct approach and to recognize again that there are two different motivations that are -- you know -- driving this and to say we will use E. Coli as a process control indicator. Potentially we will mandate the use of E. Coli as a process control indicator in the short term and, again, this would get into the same discussions of sunsetting into HACCP and the other discussions that have occurred over the last few days. But the idea is that E. Coli would be used as a process control indicator. Potentially, we would set critical limits for E. Coli for specific products. Again, the concept here is that we would set the critical limit but this would be a critical limit in a HACCP program or in a

HACCP concept that would be handled as any critical limit and that it would be the responsibility of a plant to do the monitoring. It would be the responsibility of the plant to respond to deviations from critical limits. So essentially the goal here would be to say there must be a microbial testing as an element of a HACCP program. But we would say E. Coli appears to be a reasonable process control indicator and, again, we would establish critical limits but the same discussions we've had about critical limits with regard to other critical limits could be had about the limits we would set or the use of those limits for E. Coli. Let's step back and say, well, all right, how about pathogen reduction. And that's the other side of it. And I think if you look at it conceptually the key behind HACCP is pathogen -- is identification of hazards. Pathogen reduction is a means of seeing whether your HACCP program's working or as a pathogen reduction target is something toward which a HACCP program can be designed so the concept would be, again, that we would maintain pathogen reduction targets -- potentially the same targets we have in the current reg -- that they would be phased in over a period of time and that HACCP programs would be designed to meet those targets. We, as an agency, in validating HACCP plans, would have the right to go in and monitor to see if a specific plant met our pathogen targets. Now this might be monitoring over a month. This might be monitoring -- you know -- I mean I'm not sure how we would set up this specific monitoring program -- but the idea is to potentially on a random basis we could walk into a plant and say is your HACCP plan meeting our pathogen target. If the plan does not meet the pathogen target, i.e., if the pathogen target is exceeded we would indicate there was a

problem with the plan. Again, we're not talking about lot acceptance. And I would say from the beginning, none of this is lot acceptance. What we're talking about is a way of assessing the ability of a plan to meet a specific pathogen target. We would maintain the pathogen targets. They would be the key to what we're doing because we want to ultimately reduce disease so there would be pathogen targets but we do the sampling to see if there was compliance with the pathogen targets and, again, the pathogen target would serve as a means of, if you will, validating the HACCP plan. Having said all of this, again, I would emphasize that this is current thinking and one of the things we want to do today is get feedback from you, to get ideas from you. This is where our thinking as led us -- this concept of separating out a process control indicator from a pathogen reduction indicator, recognizing we have both of these objectives. But I think at this point probably we should say, what are the comments?

MR. BILLY: All right. Again, the way I'd like to do this is to approach it, taking into account what Glenn has just outlined, and work through these billets and hear dialogue about what Glenn has said and what's captured in the paper in the context of these major issue areas. So the first area then would be a discussion about the scientific and policy basis for establishing targets. So let's begin.

MR. TAYLOR: Can I clarify what the issue is?

MR. BILLY: Sure.

MR. TAYLOR: We -- we now are talking both about having a process control indicator target or standard and a pathogen reduction target and presumably we ought to be talking about the scientific and policy basis for both.

MR. BILLY: Okay. Bill?

MR. BROWN: Okay. Are we ready? Okay. Thanks, Tom. Thanks for the opportunity to comment. Bruce keeps telling me age before beauty so I guess I qualify.

I own a testing lab -- ABC Research. We've got about twenty five microbiologists, thirty chemists. We have USDA inspected pilot plant and I'm also, in my spare time, Executive Director of Southeastern Meat Association.

Our lab has been involved with USDA and industry for about twenty eight years. We developed the 70 salmonella data for roast beef. We've developed heat resistant data for listeria monostagonese (phonetic sp.) and E. Coli. I'd like to compliment the USDA technical group on the contributions they've made and significant microbiological technologies over the years -- listeria methods they've developed, campilobacter (phonetic sp.), baseline studies, just to name a few. I think in the last two days we've had a discussion on HACCP and pathogen reduction and I think we need to separate those two because I sense that in some cases they've been put together. I think we need to remember, as Dr. Morris just pointed out, that HACCP is process control developed by industry for preventing safety problems. This includes microbial as well as chemical and physical. And in order to do this, you really need binding specifications, you need sanitation documents, and you need standard operating procedures, and you need GMP's. Pathogen reduction, as the name implies, is reducing the pathogens. Now, the pathogens come from animals, granted. They also come from the environment, they come from people, and as the last couple of years have indicated, they come

from water. When I went to school about a hundred years ago we had three pathogens. We had salmonella, staph, and clostridium that we talked about. At last count, we're up to probably thirty seven pathogens and we're increasing so it's difficult to get a handle on the pathogen reduction. We also need some help on both sides of the food processing plant if this goal is going to be accomplished. We need to have a farm to table type attitude here if we're really going to reduce the food poisoning incidents. Frank Bryan's data published in the Journal of Food Protection indicates that sixty one percent of the food poisoning cases can be traced back to food service; thirty two percent, homes; and seven percent to food processing plants. Now, in raw product, I think the food processing plants do need to maintain low numbers of pathogens but that's about as far as they can go. We need to work with the animal producers, the truckers, the livestock markets, to reduce the number of positive pathogen animals that are coming to the plant. We need educational help in the restaurants and the home to improve food safety. Working with one restaurant chain, they have two hundred thousand employees, they have an admitted two hundred percent turnover, so the educational opportunities are great on that end of the chain.

Salmonella has been identified as the pathogen to measure for the purpose of determining the effectiveness of process control. We have some problems with salmonella. A lot of the plant micro labs are located in the middle of the processing plant and it's been our opinion all along that we don't need to have salmonella testing in the middle of a processing plant. I don't think it's a good idea to do that testing in the plant.

The cost is a factor for yes or no on salmonella. To determine the incidence will cost probably twenty six to twenty nine dollars per sample. If we do most probable numbers to determine how many are there it's many times its cost. Using the alyser procedure or any of the rapid methods a negative takes twenty four to forty eight hours and firm positive about five days. In comparison with that E. Coli, the cost is twelve to fifteen dollars. Total count, probably twelve to fifteen dollars.

One salmonella per twenty five grams is positive. Ten thousand salmonella per twenty five grams is positive. There's no distinction on the number of organisms so that presents a problem. The number applies to -- especially in poultry -- is related to the incidents in the flock and we seem to have lost sight of the fact that the processing plant can reduce the numbers but they probably cannot eliminate them. In all salmonella strains, I've been told, are not pathogenic to humans.

Now, this is not good for business but I think we ought to use E. Coli, as Dr. Morris has indicated, and probably even total count in some cases, and this total count should be done at twenty degrees centigrade. And if the agency needs to measure salmonella I think that's the appropriate place to do salmonella testing.

The meat and poultry industry, I think, needs to be congratulated for reducing the incidence of pathogens and total microbial level on products over the years. Thirty years ago, probably our counts on ground beef were ten to the fifth or ten to the sixth. Recently they are ten to the three, ten to the four. And listeria, also reported by CDC, has been cut in half. On smaller plants, I think the best way to

reduce the burden on costs is to collect samples for a week and then composite these five samples. Now, it would certainly take longer to get the data but you also have a lower production rates on the plants. We also need to maintain a lactic acid fleuro spoilage organisms. I don't think we need to reduce microbial number to zero on raw meat and poultry.

Thanks for the opportunity.

MR. BILLY: I'm going to ask Pat to clarify a little bit in terms of what Glenn talked about in terms of the current thinking and particularly with regard to testing with regard to salmonella. I think it will help.

MS. STOLFA: Thanks very much. Bill, we very much appreciate your comments. I do think we'd like to make clear that in our current thinking, in fact, we are both separating the testing to measure achievement of the process control objective from testing to measure pathogen reduction and we are also separating who takes lead responsibility for that and so our current thinking is that the E. Coli testing to measure achievement of process control would continue to be an industry responsibility and, again, as Glenn mentioned, where we haven't worked out all of the details about that, but we'd certainly like to hear from you, and our notion is that the salmonella testing to measure pathogen reduction would become primarily the agency responsibility. Now, that's not to say that we would discourage companies from doing their own salmonella testing but the agency would take the responsibility for doing that testing and I just -- that is a significant change from what's in the proposal and maybe you want to tell us that we should stay with the proposal or maybe you

want to tell us something totally different but I think we want to make sure that we've been as clear as we can about -- about the change that we've put in here.

DR. MORRIS: I would also note that in terms of the E. Coli what we would envision at this point is we would indeed use a quantitative test. So, again, the idea is that potentially we would use a quantitative E. Coli test as a measure of process control but, again, that would be the plant. The plant would be using that as a measure of their process control with, again, potentially the establishment of critical limits. But it's a different conceptual framework than what -- than the concept of using salmonella as a means of moving toward pathogen reduction and as a means of assessing potentially the validity of a HACCP plan.

MS. DEWAAL: Caroline Smith Dewaal, Center for Science in the Public Interest. My first response is simply that the reason we aren't talking about testing for lot acceptance is because the technology -- the rapid microbial testing technology doesn't exist today. That's the only reason that we're not talking about it for lot acceptance. We understand that. We have endorsed testing -- microbial testing for process control, not a holding test scenario, but a testing for process control. But I do want to remind the agency that is the only reason that we are not using it for a more stringent enforcement purpose.

Now, the reason the technology doesn't exist is because despite the fact that the National Academy of Sciences told this agency in 1985 that they needed to push HACCP forward and they needed to push for development of rapid tests that was not done. We are now looking ten years down the road at the fact that a lot of the tests don't exist

or where they do exist they're too expensive to mandate their use on a regular basis. My concern about the proposal that you put on the table today is, number one, it doesn't -- if the industry is doing -- is required to do E. Coli testing for generic E. Coli where the tests exist and they're relatively cheap and the agency is required to do testing for pathogen development, I think it's going to slow the development of the pathogen specific tests. That's my number one concern. There won't be the demand for them and it's going to slow down the development of the technology.

The second is that I have very significant concerns about the agency's ability to fund a major testing program for pathogens and this really comes from my experience with the Food and Drug Administration where the agency can have the best standards in the world, assuming they did, but if they don't have the money to test for them it's meaningless from a consumer perspective and we end up with a system where, as Dr. Kessler has so well articulated, we have them chasing the horses after they've left the barn and USDA will be out running around like they are today trying to figure out how to address pathogens in the food supply after they're already in the food supply. I think -- I mean I think your proposal is very interesting but my concern is that unless you mandate pathogen specific testing by the industry it's really going to slow down a lot of things including the pathogen reduction goal that you have.

MR. BILLY: Speak up.

MR. JAN: Lee Jan with -- representing the State Director's Meat Poultry Inspection. I'd like to applaud FSIS's direction or redirection to select an organism like E. Coli. It's my opinion that that's the true

test of process control. If we go and look at specific pathogens to determine process control we miss the other pathogens that we're not looking for and all species -- all animals -- do not carry the pathogen that we're looking for at all times so we're not testing process control and we have a lot of false positives. I think that that's great.

I would have some questions. The records, as you're proposing the E. Coli testing at this time, would those records remain in the plant for review by the inspectors or would they be submitted for some -- for -- like was first proposed that salmonella submitted for some kind of data collection? I would think that probably in this case keeping them in the plant as we proposed for HACCP would be the way to go. And I would also want to insure that if we're talking about doing this almost like a mandated mini HACCP or a portion of HACCP almost immediately that -- that the frequency of testing be established by the plant's needs so the plant that doesn't kill very many wouldn't have to test necessarily every day.

MS. FOREMAN: Tom, may I?

MR. BILLY: Sure.

MS. FOREMAN: I want to go back -- I'm sorry -- I'm Carol Tucker Foreman. I'd like to go back for a minute to kind of a basic principle which is that this is supposed to be a public health program. Ninety -- the Food Marketing Institute, which has been surveying public opinion on food safety and cost issues for about twenty five years now, has put a question about bacteriological contamination of food into their survey for the first time this year and as a result -- the response they got was that ninety one percent of their very large sample -- over two thousand people -- found that bacterial

contamination of food was either a serious or a very serious public health problem. I think that means that we have a problem that has to be responded to very forcefully by the Department of Agriculture saying we are going to take steps to protect public health. Process control is important but actions that protect public health have to be the goal, the primary goal, the secondary goal, and I'd even say the tertiary goal of this program. The taxpayer spends six hundred million dollars a year to inspect meat and poultry. Every piece of meat that goes out of an inspected plant carries a seal that says that your United States Department of Agriculture endorses it. And they created the Office of Under Secretary of Agriculture a couple of years ago. The Department of Agriculture last year -- the Department of Agriculture -- the Congress specifically said we're going to have a public health program within the Department of Agriculture. That changes, I think, by law a lot of history here that says this is a quality control program, this is an animal disease prevention program. This Congress has now said this is a public health program. Where process control may lead to a reduction in public health problems but I think the Department's under an obligation to make the pathogen reduction aspects of your proposal the primary aspects of it. You are not going to require each plant to test for salmonella or some other human pathogen each day. Therefore, all of this product is going to pass out of plants with a seal on it that says inspected for wholesomeness which, whether we like it or not, clearly the public believes says that it's safe to eat. They may not believe it anymore but that's clearly what it was intended to convey. And the product may not have been tested at all and there may not be any -- any

assurance, any indication, any even incentive to make sure that it's pathogen -- as pathogen free as possible.

I'd like to follow on to what Caroline said and that is that we've been supportive of the direction the Department's going on the testing up to this point because it's clear that history makes it not possible for you to go much further. History should also not let you take a step backwards at this point. For many years the Department argued that it had no authority to regulate pathogens in raw meat and poultry. I think that it is clear that that wasn't the case originally. I think the courts have indicated now that it is assuredly the case that you can and I don't believe anybody's really arguing seriously. The question is how we get there. We would be able to do it better if the Department didn't have this unfortunate history of saying it didn't have the authority so it discouraged the development of tests and mechanisms to control pathogens and to regulate the pathogen levels in food. Somewhere along the line you got to take the bit in your mouth and get over twenty five years of misjudging history -- twenty years -- and get on with doing what the National Academy of Sciences recommended in 1995.

If Congress has already cut forty million dollars out of your budget for this year I don't where the Department thinks it's going to get money to train inspectors to implement this new inspection program and for the Department to implement a salmonella testing program. We obviously would like for the Department to come along and have its inspectors check from time to time the accuracy of the testing done by plants but to have you rely only on USDA testing and not require plants to do some salmonella testing I think diminishes

the value of this proposal very substantially, even if it is funded and I think you have trouble having it funded.

One last point here. I think it's an invitation to unfair competition. Those plants that want to do it right, the companies that care will be doing salmonella testing regularly. The bottom dwellers -- the people that you were after by setting the industry median as a starting point here will be free, and I'm sure none of them are in this room because surely nobody would come here if they're among that group they wouldn't be here participating in this, but they're there. It's clear they're there. The median is the median. Half of the people are down there. And they should not be allowed to continue to put those people who do it right at an economic disadvantage and to be a threat to public health by continuing to operate the way they have in the past. And this process of having USDA do all of the pathogen testing really relieves that particular group of the responsibility that ought to be their's.

MR. BILLY: Dane and Rosemary sort of had their flags up. Okay, Dane, go ahead.

MR. BERNARD: Dane Bernard, National Food Processors Association. First of all, I'd like to say that having Caroline sitting beside me during this discussion is probably not the best situation because if I get too far out of line she's liable to do me in over here because Caroline and I have discussed this topic many, many times and I think in order to get along we've agreed to disagree on this particular point.

Let me go back to Dr. Morris' presentation, if I might. He mentioned two concepts as our starting point. The first, I don't think

anybody has any disagreement with, and that's the need for pathogen reduction. That was the first point. I don't think anybody in this room has any doubt that that's what we're about. The second item he mentioned was -- the second concept was on the importance of microbiological testing in process control. That phrase mixes two things which -- you know -- as we go down this debate, and obviously there will be a lot of things said, I think we should consider that process control and Carol said that pathogen reduction may be achieved by process control, I think if we are to commit to HACCP that is what HACCP is about. By having better control of the processes through good well established HACCP plans we will achieve pathogen reduction. I said yesterday that in too many food plants what we have done is reduce the number of critical control points to one and that was whatever the inspector wants us to do at that moment in time that day. I submit to you that if we put too much weight on microbiological testing we will achieve the same thing. The focus will become the microbiological results of the day, not the proper emphasis on HACCP. I said yesterday, everything we do from this point on if we're to commit to HACCP should support it. My contention is and has been that setting rigid microbiological standards then becomes the target, not continual improvement through process control which should be the target of HACCP. Now, having said that, microbiological testing has a role to play. We have never denied that. That role will vary depending on what industry segment and what product you're talking about. Could that include pathogen testing? It could. But it depends on where you're talking about, so my feeling is yes, microbiological testing is important. It

has a role to play but we should not through our efforts make that the central focus so that it subverts all of our efforts in trying to put in a process control system which, as Lee Jan said, will set us up for the next challenge. If we target specific pathogens and that's our target we're only testing for what we know today. We need a system that's responsive to tomorrow and the next bug that Mother Nature throws at us or the next challenge it throws at us. And unless we get to the point where we have good process control and we have educated people running the plants and get the good training on line we're not going to be there. So I think we need to look at microbiological testing in that light.

MS. FOREMAN: May I ask Dane a question? Dane, what do you do with a plant whose -- where their desire for the end result is a product that is of low microbial quality as well as low shelf life quality? What do you do with the plant whose standards fall below what we all think would be appropriate to go out with a USDA seal on it and they set up a HACCP plan to reach that goal? They have process control but should it have a USDA seal on it?

MR. BERNARD: I won't comment on the situation with the seal, Carol, but in terms of a sub-standard operation nobody in this room is going to come in here and defend this kind of operations. We heard some horror stories the other day. The agency nor the industry should have to put up with those kinds of situations. We support appropriate action to get those kinds of people out of business and -- or to make them correct their operations. We talked yesterday about validation and the need to be crystal clear what we mean by validation of HACCP plans and that has to have some performance criteria attached to it.

We're going to talk today about performance criteria but those can take many forms and end product microbiological specification may be a proper form for certain items in certain areas. By the same token, performance criteria which would achieve and accept end result may take other forms but the central focus is no, we should not defend sub-standard operations and we should do what we can to get those out of existence. And we're not going to utilize if we allow HACCP to become a disguise for a product that should not go on the market then we have not completed our mission. HACCP cannot be a stamp of approval for product that should not go on the market.

MR. BILLY: I think what I hear in Carol's question in that example the -- in that circumstance what -- how would -- if it's the agency or the state role then to take action to prevent that and they have a HACCP program which they're meeting but she characterized it. The products the products they're producing are below a standard industry and government would like to see, what leverage -- where would the leverage come from to take action, whether it's in verification or however under a HACCP scenario absent setting some sort of limit that would be a measure of effective process control? I mean how would you do it? You'd look for something in sanitation or search? How would you make it work?

MR. BERNARD: I'm not sure exactly where that sub-standard product would come from. If we have -- and I've said before that we need good HACCP plans. We just don't need pieces of paper that look like HACCP plans. We need good HACCP plans. If they are good plans and they are validated and you have built in to those HACCP plans performance criteria like we talked about yesterday -- a 70 cook for

salmonella, for example.

MR. BILLY: How about for raw product?

MR. BERNARD: And if we're observing that HACCP plan we should be producing good product. If, on the other hand, the plant has a good HACCP plan and is following those kinds of things but not doing a good job on the basic programs, the sanitation, the inspectors should be able to pick up those kinds of things on an audit and take action. You know -- there are several vehicles for dealing with those kinds of situations.

MR. BILLY: I appreciate what you're saying but we're not answering the question.

MR. POCIUS: Tom, can I? Let me jump in there.

MR. BILLY: Sure.

MR. POCIUS: This is Joe Pocius with the National Turkey Federation. If you set performance criteria for the HACCP plans vis a vis the E. Coli, then they have to meet that or else their HACCP plan, as I understand the proposal, would be invalidated. They'd had to go through a revalidation and all that. They can't operate at that sub-standard. They have to meet that performance criteria. And what I understand the real question to be is not performance criteria based on E. Coli but rather one based on salmonella. And I have a question to the agency on that. It seems that -- my concern is how will the salmonella data that you collect be used? If you compare it to a set of numbers or -- let me get my notes straight here -- will you use as a comparison to a set of -- a set standard or will you use it to actually measure pathogen reduction? If you're looking for pathogen reduction, even on a national basis, then you have to look for the trend

within the industry because that gives you your trend to reduction. If you set it to a specific number, in particular, as Glenn had mentioned, a percentage rather than a quantitative number, then what you've really said is zero cause you've either passed or you've failed. If there's one there you fail. Zero is your tolerance. Everyone in this room at one time or another has recognized publicly that zero is not achievable. So my concern there is how are you going to use the information on salmonella that you collect?

MR. TAYLOR: Joe, let me take a shot at just conveying, again, current thinking so that these deliberations and the use to which we put salmonella results under this construct really builds on the proposal. And as you recall in the proposal what we said was that we would set targets for incidents of salmonella contamination for each species based on what we know about current incidents. And we proposed setting the percent incidents target somewhere below the current average on the theory that if every plant currently operating across the spectrum above and below the current average could be held accountable for meeting the current average that would achieve in the aggregate pathogen reduction in the sense that the national average percent incidents would come down and consequently the quantity of product going out in commerce with detectable salmonella would decline and have a public health benefit. The idea as proposed was that the plant would do daily testing to verify whether their processes were operating under control to achieve that target on a consistent basis and the preamble laid out our intention in monitoring these data being where the results of being in a position when the evidence says that the plant is not consistently controlling the

process to achieve the target then the remedy would be that we would require the plant to address the process control problem that was resulting in a failure to achieve that target. What we're thinking about is, again, limiting the plants' testing to E. Coli as a fecal contamination indicator. Having a performance standard for salmonella that conceptually is identical in terms of the use to which it would be put to what we proposed except that the testing obligation and compliance monitoring, if you will, would be the agency's regulatory responsibility in effect and we would have to devise strategies for going in and testing ourselves. It might be very different. In fact, again, this is where our thinking is not as developed as it is on other concepts. We'd develop some way of going in and testing in effect to enforce these targets and then what we would do with the results if we find that a plant is not meeting the target we would require correction in their process control to achieve the target and --

MR. POCIUS: Right. And we have no -- matter of fact, I have no arguments against what you've said. It's how the agency may go about doing that and I want to set up a little scenario here so you understand what my concern is. In the poultry and meat industries, particularly in the poultry industry where we also control our animal production, we know that certain times of the year we will have spikes in our micro load. We just know that. We don't know why. Usually during the summer in the south if different conditions exist. If you have a hard set number and we have these spikes in these areas you will naturally fail this set tolerance that we come up with. On the other hand -- and we're not talking -- in a cooked process you can

achieve a 5-D, 7-D. Canners can achieve a 12-D reduction. And you can do that all the time. In the interventions that we discussed over the past two days we discussed them in terms of a 1 log reduction. Well, if that intervention is in control and it's achieving its 1 log reduction but because of conditions that we really have no answers to our micro load is higher than it is at other times of the year you can fail that set number tolerance. It's a trend that you need to look at rather than a hard number.

MR. FOREMAN: Is it okay then to say to the public when they buy turkey in the summertime that they should be aware of the fact that it's likely to have -- raw turkey -- that it's likely to have a higher level of salmonella contamination. You can get the same seal in the summer that you get in the winter. Perhaps your process controls should be altered so that you have more stringent line operation during the summer in order that you come out in the summer selling the public a product that is similar to that that they get the rest of the year cause the public doesn't know that.

MR. POCIUS: The seal indicates that the product got the same inspection at any time of the year.

MS. MACKLOW: The seal says it's wholesome.

MR. BILLY: Rosemary?

MR. POCIUS: And that indicates in the C.F.R.

MS. MACKLOW: Thank you, Mr. Billy. Those of us who spend more time walking around meat plants and meeting with everyday problems are not really as comfortable or atoned in this big public debate that we're having here but we do bring a sense of what really is happening out at the grass root level of this great industry that has been putting

meat and poultry on the table for consumers for a long time. I've listened carefully to the debate over the last two days and there are a lot of demands on this program -- a lot of demands that we still want people to look at the plants, we still want people to see how things happen out in the field. Suddenly today we've gotten that and there is a sense that we ought to focus everything on that microbiological view of a product and I appreciate enormously what Dane Bernard has said to put that into a general focus. We all know that a meat inspector who really only targets one critical limit or critical point in a HACCP plan in a program in a plant may indeed ignore a lot of other things that are happening. So this is one component. It's a very important component. And it's taking us all into new areas that have not really been tested. One of the great concerns that we have as an industry is that we will be establishing standards for people without good baseline data and that baseline data would -- I'm encouraged to hear the way in which you're bringing your program forward and your current thinking. I think it's extremely important that once we have that thinking described for us that we go out there and get some data to make sure that it's going to work before we start mandating an entire nation and maybe other nations are trading partners who we've heard from around this table during the last couple of days to do things that we haven't really tested yet. And, so, I think that's a very important component of how we move forward. It's all progress towards where we need to be. We can't make a sudden night and day change.

As I told you all on Wednesday, I just had some recent OE experience and one of the comments that was made in that may be

germane and then I'd like to cede the rest of my time to Dr. Acuff who's sitting here beside me and that is that it's better to go out and count the haystacks rather than to hunt for a needle in one haystack and we're dealing with such a huge industry. We would be better to be looking at the big picture than so focusing our effort. And as somebody described to me this morning, if we really start hunting for salmonella we'll come up with lots and lots of negatives. It doesn't tell us much. Now, the microbiologists are going to have to explain that. I can't explain that to you. This is a complex subject and -- you know -- we're here to talk about that very specific issue today and I'd like to turn, if I may, my time over now to Dr. Acuff.

DR. ACUFF: Gary Acuff, Texas A&M University. I think it's important in some of the comments that have been made that we not uncouple safety and process control because I think there's been a slight attempt to separate those. If our HACCP is designed for safety, process control is in control of safety and any amount of testing is not going to show that we have a safe product. Process control is. It's also been said that we don't have the technology to test and that we need to develop this technology. You know -- I think we can always improve technology but technology is not the limit. It's simply statistics. You can't test all the food or there won't be anything to eat. And the only way we're going to have reliable indicators of whether a pathogen is present or not is to test increasingly high levels of food, whether we use PCR or conventional tests. You have to test increasing high numbers to be able to detect the pathogens because they're in extremely low levels and they're not equally distributed.

Now, I don't envy FSIS's situation in trying to convince the consumer that they have improved the situation but if I had to go to the consumer I would rather look them in the eye and tell them that I have improved the situation with process control verification in my hand than a bunch of negative pathogen tests because I don't think you have anything there.

Now, I did have one question for Dr. Morris. One of the things that I picked up on when you were speaking was the mention of critical limits for E. Coli and I'm actually looking for a clarification, I guess. Critical limit, as far as I have always used it, refers to specific critical control points and which I agree is the way to verify this situation that we should have critical limits designed for individual processes at CCP's.

Are you discussing critical limits or end product standards?

MR. TAYLOR: Dr. Acuff, let me just -- before Dr. Morris responds on that point let me just in interest of clarifying what our strategy is just say how fully I agree with your observation that microbial testing or any kind of end product standards in the absence of process control is woefully inadequate to produce -- you know -- to achieve food safety goals and provide the assurance that the public expects. That's why we're proposing to mandate HACCP. Our conception is, however, that process control and some measure of performance -- you can call it HACCP verification, you can call it measures of accountability for reducing pathogens, call it what you want, but HACCP without some way to verify that we're achieving the public health goal of reducing pathogens is also by itself inadequate. Process control for process control sake doesn't get us anywhere so I

agree with you completely and I think when we approach testing and standards -- performance standards -- targets -- I mean we have to go it in a way that takes account of our reliance on process control as the instrument for achieving a goal. But then the question is, how do you know if you're achieving your goal and critically -- I mean for our strategy -- how do you have some incentive for the plant to work to improve? And our theory is that unless there's some accountability for achieving some concrete food safety result and in our mind that means reducing pathogens there is absent from the system an incentive to improve and that's what we're struggling for is an effective incentive in the form of a measure of accountability for reducing.

DR. ACUFF: I don't disagree with that and, in fact, -- you know -- part pathogen testing on occasion is an important part of verifying the HACCP program. I mean if you designed it for safety situation then you have to come in and verify on occasion the hazards that you're trying to control. But when you have a situation where the pathogens are present at low levels and not with equal distribution like we have in many cases in the beef industry, for example, I think that your stronger and more reliable verification is verifying CCP's and looking at records and that sort of thing but it certainly can be supplemented with pathogen testing but I'd hate to rely on that exclusively.

MR. TAYLOR: Right. I'd agree.

DR. MORRIS: And, again, I think we're saying the same thing. We're saying it slightly differently but we're saying the same thing which is that we see the ultimate goal target as being pathogen

reduction and we have to measure that and that that's something that potentially the agency would do as a means of verifying HACCP plans but at the same time we recognize that there needs to be process control and so what we are saying is that we recognize that E. Coli is the superior process control indicator. And, again, this is conceptual and -- you know -- I'm not totally sure everybody sitting at this table would agree with all of the details at this point in time -- you know -- let me clarify that before I dig myself in too deep -- but at least at a conceptual level I would see the E. Coli testing as being part of the process control process and we would use the same terminology we have used with other process control indicators, i.e, the agency would establish, at least as a starting point, critical limits but they would handled as critical limits would be handled as you would do with any other process control indicator. So in other words, if the critical limit was exceeded then there should be something in the HACCP plan which indicates what the plant does. I mean, in other words, the E. Coli testing would be part of the on-going daily this is our process control plan and that we would standing back as an agency just as we would check on every aspect of the HACCP plan this would be something that we would monitor. But that the concept would be that the process control E. Coli testing would be in control of the plant.

DR. ACUFF: Okay. But the critical limit is for CCP.

DR. MORRIS: This would conceptually be as a CCP.

MR. BILLY: I need to say something here.

DR. MORRIS: Again, it's obvious what you're finding here is there is --

MR. BILLY: I'm not sure that it would be necessarily a critical

limit but it might well be a standard -- performance standard against which various critical control points and limits appropriate to those points would be measured by an E. Coli standard of performance and I think in the HACCP context I think that makes, at least for me, the most sense in terms of how we would apply this in the HACCP setting.

DR. MORRIS: But, again, I would ask -- you know -- this is why we're here. Obviously, you can see that there are differences of opinion even internally. What I would ask is how would you -- Gary, how would you handle it? What would you do?

DR. ACUFF: Well, that is a good question. I guess I would answer that with a question. I sit on the Secretary's Advisory Committee on Microbiological Criteria for Food and one of the things that we have been asked to do in this latest quarter is do an extensive literature review and collect data regarding the use of indicator organisms in meat and poultry and my assignment has been beef slaughter. So I've spent the last couple of months collecting data and looking at the literature that's out there and what I have found is a great disparity in what data actually says regarding the ability of E. Coli, coliforms, APC's to indicate really very much of anything. In addition to that, I have been able to anonymously solicit data from several beef processors and we've collected several years of data and we have taken this and taken the names off and made sure everything remains anonymous and have done some rather extensive analyses and we see also that there are no correlations with any of that data. So --

MR. BILLY: Correlations with what?

DR. ACUFF: With E. Coli, fecal contamination, pathogens. The

indicator situation is not clear.

So I guess the way I would answer your question is I would not be excited about putting many of my eggs in the end product verification basket. I would be more confident in verifying certain critical control points that I feel are controlling the process and if I -- if I feel that the CCP's are under control and on occasional end product testing for pathogens if you want, and maybe even for E. Coli, then I feel confident that the process is in control. So I would like to see critical limits at CCP's, not simply end product standards.

MR. BILLY: Okay. Bob?

MR. HIBBERT: Thank you, Tom. I think we may be sewing some -- my name is Bob Hibbert for the record. I'm here on behalf of the Eastern Meat Packers Association. We may be creating some confusion by being a little inexact with the term standards. The -- and I think that gets us -- it may be useful at some point for the Department to pause and do some sorting out and articulating of what it believes its authorities are in this area. That hasn't happened yet. What we have now, at least on the record buried in a rather lengthy proposal, is a couple of conclusory sentences that sort of say well, we have this Meat and Poultry Inspection Act and we have the authority for everything we're doing here and I think we need more, both because that's the Department's job, number one, and, number two, regardless of the outcome I think we're going to have better decisions in this area if the Department engages in the discipline of thinking through what its authorities are and aren't. The -- as Mike Taylor said, this is a bit of a new paradigm that you're thinking about adopting and I think that dictates that kind of analysis and I think

while it's quite true as was pointed out, there has been some recent precedent which clarifies the Department's authority to conclude that in some instances, at least, products containing pathogens may be adulterated we are talking today about a really separate question. We're talking about the question of not an adulteration question but of something else of mandating tests which are not determinative of adulteration but indicates something else. Now, if we -- and I think that raises the question. Once you de-link from your adulteration authority I think you have to stop and ask, what is our authority? And I think the difficulty for many people with the proposed sort of freestanding do a daily pathogen test was it wasn't clear to anyone I talked to just what that authority is. Now what we're hearing today is obviously something different which seems to create some linkage, perhaps not with the adulteration standard, but with process control. That is -- my reaction is that is the step in the right direction but regardless of the outcome I think the Department has to be more careful than it's been. Any comments from counsel today or any other time today would be helpful as to what it really think its authority is in this area because it's blazing some new trails and it hasn't bothered to tell us yet how it thinks it has the basis to get us there.

MR. TAYLOR: We, of course, have abundant legal authority to do whatever it is we're doing here.

MR. HIBBERT: Thank you.

MR. TAYLOR: Let me make just one very broad observation. I don't purport to be the legal expert here. But -- you know -- the adulteration authorities in the statute address not only whether specific contaminants render products unhealthful which was the

basis upon which we reached the conclusion we reached regarding 0157 in raw ground beef but the adulteration provision of the statute also addressed, for example, whether the unsanitary conditions in a plant may render food injurious to health, and that's an adulteration provision that ties very closely to the concept of process control and I have one more conclusory sentence on this subject. We have broad rule making authority to define the conditions under which an adulteration provision such as that -- addressing unsanitary conditions -- would be deemed to be violated. And so we would need to go through rule making to define those conditions but that's what we're doing.

MR. HIBBERT: Just one comment on response. I think it would seem by process of elimination that -- that this would have to be based on some sort of sanitation theory. I guess I would just ask the Department to consider the hypothetical situation of let's say a plant which grinds chicken, which is immaculate, and which has perfect controls, and which is purchasing chicken which is above -- which has the USDA mark of inspection on it which is marked as inspected and passed and which has salmonella levels above the baseline. I don't know what the Department's theory would be for saying that there's a sanitation problem in that plant.

MR. TAYLOR: We will consider that hypothetical.

MR. HIBBERT: Thank you.

MR. BILLY: Nancy?

MS. DONLEY: Thank you. I'm Nancy Donley with STOPS -- Safe Tables Our Priority. We are a consumers group and I would like to specifically address a hypothetical from Mr. Acuff, is it, who said

that he would challenge FSIS to look the consumers in the eye and tell them that you have put in place process controls. My response as a consumer would be fine, but is it safe to eat? Process controls are specifically that. You are controlling a process. It doesn't say at all whether the process works, doesn't work. You have to have something that says the end result is indeed safe meat and poultry. I kind of equate it to if someone were to put a schematic in front of me of a computer -- high-tech computer operation and I would look at it and oh, yeah, yeah, you can see it right here. Yeah, but does the program work? Consumers -- that's all they're interested in is the safety period, not what process controls go into it.

I'd also just like to say that -- once again reiterate that I can't tell you enough how pleased I am to see the whole HACCP proposal and we're very, very firmly behind it. I would like to say, however, that it appears to me that the process controls has been looked at and has -- a lot of thought has been put into it as far as the process control program goes but it appears to me that the pathogen reduction portion of this has really been -- is almost an afterthought. Looking into this and going into -- first of all, I'd just like to say that looking -- sitting -- going now and reversing this using salmonella as the -- for the process control and changing it instead to E. Coli, I just want to caution again from a consumer's viewpoint that -- you know -- E. Coli right now is a hot button period. It's getting some recognition in the news. We just have to be -- I'm very concerned that if we're going to be letting it out that hey, we're putting in process controls for E. Coli it's going to send off a very, very, very misunderstood and dangerous message to consumers. I just want to put that right in because the

pathogen that consumers are aware of and don't know of it is specifically the 015787 strain. I just want to kind of get on record with that.

I have a couple of problems here that with process controls that it's testing for fine for E. Coli. We still have a detected and ship it anyway plan. There is nothing right now that is saying that once fecal contamination has been found to be present in food that anything's going to be done about it. We're going to so note it and ship it anyway. I'm very, very, very concerned about that. We are going to have food-born illnesses as a result and it's -- to me it doesn't seem to be addressing the problem then of pathogen control. We are identifying -- acknowledging a problem and allowing it to continue. Once -- once product gets out and gets out into the consumer's hands it's too late. You can't -- it's too late, it's too difficult, and too expensive to mop it up.

I'm going to share a little bit too as far as -- let me digress. I also -- if I understand Dr. Morris correctly that when we get into the actual pathogen reduction that we will establish and maintain targets for that but that salmonella will be the -- the pathogen -- the -- the control?

DR. MORRIS: That's one possibility. Again, I think this is something that we would -- I think the major concept here is the idea of separating out pathogen reduction from process control. I think there's a lot of discussion that still needs to go on on both sides of this issue. Obviously, as Gary and I and Tom were talking about the specifics of process control and the indicators to be used there, I think similar discussions and there will be similar issues as to the

appropriate pathogens to be used as pathogen targets. I will say, again, sort of in my own note, one approach would be to use the targets that we have already put into the regulation as our pathogen control targets. Again, there was a lot of thought and a lot of logic or at least I'd give you some of the logic that went into that. I think that ultimately, as has been said before, this entire process needs to be recognized as a dynamic process that we may set specific targets -- pathogen targets at this point in time -- but this does not mean those will be our targets for fifty years. This is a dynamic process. As the industry technology changes, as our understanding of public health changes, as other things change -- you know -- potentially we will come back and look at different pathogens and different targets. Again, it would be through a process similar to this -- you know -- but I think there needs to be recognized that we are not making the decision now and forever that it will only be salmonella but at least for right now that may be a reasonable starting point.

MS. DONLEY: If I can just make a comment to that also and this also is something that Carol Foreman has alluded to. Salmonella, to my understanding -- I'm not a microbiologists by any -- and not even a pseudo microbiologist as has been stated before -- but I -- I -- to my knowledge there has been no correlation made between the presence of 0157 along with salmonella as a for instance and that concerns me. Particularly that it is something that -- that if indeed that is the only thing and so I would strongly suggest that in the case of ground beef products that 0157 would very definitely be something that would have to be tested for.

The -- the -- I think also the fact that -- I know what -- I want

to digress -- you said we're going to be doing random samplings. If I'm understanding the program then correctly for pathogen reduction we're really not doing anything that is that much different than what we are currently doing right now is what it's sounding like to me. That you have been doing as far as we've got the five thousand random sampling tests that are going on right now but other than that you haven't put a number on it. I know you're still working out these particular details but still what my concern is is that even if we have a random sampling type of program going forward that there are still those -- I don't know if there's any smokers in this room -- but everyone -- there are those of us -- it's a human nature -- to think that you're not going to get caught. I'm going to smoke cigarettes but I'm not going to be the one to get the cancer. I'm very concerned that once again is that there is going to be contaminated product getting out if there's not a program that is put in to test for these things specifically. Right now the program as it stands is that we are going to be shipping out contaminated product. It just won't get caught.

MR. TAYLOR: If I may just briefly clarify a point with regard to testing and the notion that it would be random testing. I think obviously this, again, our thinking -- we need to invest more thinking about this but our concept really isn't that it would be random testing. The concept is that the target would be, in effect, a regulatory standard against which we would hold companies accountable for process control adequate to achieve a target and in order for that to be effective in doing what regulatory standards are supposed to do; that is creating a concrete incentive for companies to improve their process, to meet a certain standard, we would have to

have a compliance presence adequate to insure that companies have that incentive and then adequate to insure that we have a high level of confidence about who's making it and who's not so that we can take corrective action with respect to those who are not making it. So we would need to devise testing regimes so that we could really target our efforts on plants that aren't making it. And if you just think, if you take first blush sort of -- again -- poultry industry, the salmonella target we proposed there -- you know -- the sense is that there's an opportunity for reducing incidents of salmonella in poultry, well we could take a very -- we could take a sweep through the finite number of broiler plants in this country with intensive sampling over a period of days at any particular time of year and get fairly quickly a picture of who at that particular time has process control that's meeting this standard and who doesn't and there will be some that will be more than meeting it, there will be others who would not be meeting it and then we would, in a compliance monitoring mode, be able to do further testing and oversight and whatever compliance and inspectional activities are necessary to bring plants into compliance with this standard or plants that are unwilling or unable in due course would -- we have all the remedies available that we have now for plants who don't meet regulatory standards. So we don't -- we have not developed the details by any stretch of compliance -- you know -- monitoring plans for this. We need to give intensive thought to it cause we need to be able to talk about this with people and it will vary from species to species but it's not -- it's not like -- it's not random sampling like the -- you know -- the random sampling half of our 0157 sampling program. That's not really what we have in

mind. I think what we could envision as a compliment to compliance monitoring is some -- continuing our survey work to measure national trends so that in addition to holding individual plants accountable for reduction we could also have some parallel surveys that would measure national trends but it would be anything but random.

#2 MS. DONLEY: Could I make just one final comment and then I've taken more than my fair share of time here.

I'd just like to say that particularly in the case of 0157 that is something that is -- I don't think that there's anyone here in this room that will argue with the fact that it is such an extremely virulent bacteria. In the Journal of the American Medical Association has identified E. Coli 0157 as among the most biological substances known to man. And speaking from watching what it did to my own son and literally shredded my son from the inside and liquified portions of his brain, this pathogen cannot be allowed to go out in any way, shape, or form. It has to be zero. There can only be acceptable standards for this particular pathogen has to be zero. It takes a couple of microbes to kill a child so I would really like to see that that becomes something within this program that in these cases it's something that has to be tested for. This is not a pathogen that can just be sloughed off and you're ill for a day or so. So I really, really, really would like to see something in this pathogen control portion that address 0157 specifically for where it is in the meat product that it is the highest risk and be addressed very, very, very strongly.

MR. BILLY: Gary has something he wanted to say right on this point.

DR. ACUFF: Gary Acuff, Texas A&M University. I think it's

important that we do not confuse micro testing as a method of control. Micro testing -- FSIS should use micro testing as a tool for verification -- one of the many tools that they have. And as interesting and as, I guess, attractive as micro testing sounds it may or may not be the best tool for every purpose in every instance and FSIS needs to address their verification to fit the particular instance of trying to verify. You know -- I don't want anyone to misconstrue that I am against micro testing. I have no problem with micro testing when it's used effectively and when it's used to reach an end product -- I shouldn't use end product -- when it's -- when we are trying to find a conclusion. My problem with end product testing or micro testing is that for control let me just say with all of my being it doesn't work for control. You cannot control. I want to see something better than that.

MS. FOREMAN: Could I -- my point is to that as well because I obviously I don't want to be in the situation of seeming to endorse testing without process control. On the other hand, I'd like to make two points. One, it has been the long history in which we chose -- in which the Department chose to view pathogens on raw product as not adulterants that has left us with the little teeny bit of information that we have. We don't have good information on infectious ghosts or ghost response for various groups of people. We don't have rapid tests. The 1995 Meat and Poultry Report urged -- said USDA really should already have had the rapid tests by then -- urged the development of the data that would make it possible to do this. As recently as 1993 there were people getting ready to bring suit against FSIS because the agency had been so recalcitrant in letting

companies come in and show the virtue of the rapid test that they were developing. There has been a paradigm change here that says we need to do this. We all recognize that the existing data are not very good and the tests aren't very good. There needs to be an incentive in this program if this is to be a public health program to encourage the development of data on -- in those response mechanisms for a wide variety of pathogens and for rapid tests to detect those pathogens not in place of process control but in addition to process control because the end result here is to find ways to reduce pathogen contamination in order to improve public health, in order to keep people from getting sick. One of the things that concerns me about just USDA doing the testing for salmonella is that if everybody out there has to do salmonella tests there becomes a huge market for people to serve and you aren't a huge market even though you're big. So I would like to see the marketplace encouraged to get into the pathogen reduction business. I have this endless faith in the genius of American capitalism. If there is a market they will come both with data about those response and about tests and the absence of that incentive has held us back. I would like to see that remedied so I do have some concerns in addition to the others about USDA being the only one doing the testing.

MR. BILLY: Steve?

MR. KRUT: Steve Krut, American Association of Meat Processors. I would encourage FSIS here to be very honest with itself and with those folks in this room regarding the establishment of goals for what it hopes to achieve with this overall proposal. In the early language of the February 3rd announcement it talked about a

ninety percent reduction in food-born illness in meat and poultry. I would hope that the Department would either fully substantiate that line of thinking or be very realistic with what it hopes to achieve. As Carol Foreman said earlier -- you know -- we know that if we go forward with the program we now have an average of fifty percent of the few plants that are going to be above and fifty percent below that level. With some improvement we're still going to have some that over average and some that are under average so I think it is incumbent upon the Department as it sets forth in this direction to establish what is a realistic goal, what it hopes to achieve. We acknowledge, and I think everyone in the room concurs, that we will not eliminate all food-born pathogens. That's just -- the World Health Organization and every other group that has any scientific basis looks at that and says we will make an effort to reduce and I think if we are asking plants to come forward and put forth new processes, controls, and new systems we need to know what's expected of them; that they're not being asked to hit a target that's not identified; that if we have established a one year or three year or a five year goal that we're looking at a fifty percent reduction in the specific pathogen or overall on a grid that's fine but I think at this stage we don't have those expectations detailed and we need those very seriously and I'm saying, not tongue in cheek, but if we have an effort to reduce ninety percent of food-born illness in meat and poultry we certainly have to look at those areas beyond the jurisdiction -- the present jurisdiction of FSIS. There are probably as much -- I would suggest as much product produced outside the realm of inspection as there is under inspection and we need -- or it

is further processed, handled, transported, what have you, we need to deal with that question if we're serious about looking at a figure anywhere near ninety percent. And I'm going to suggest one last concern we have is that when you get a plant that has reduced -- reduced -- reduced a specific pathogen with all the areas within its control you're going to find, as Joe Pocius said, that sometimes seasonal factors, weather factors, lot control, and livestock situations that are beyond the control of that plant and so that when we look at what happens to the plant does that mean that their HACCP program, their inspection is pulled when things happen well beyond their control and I think we seriously need to look at that. Thank you.

MR. BILLY: Okay. I think that just before we break Secretary Glickman would like to say a few words.

SECRETARY GLICKMAN: I just want to say that this is very interesting. I visited our meat research lab in Nebraska a few months ago and I asked the question, where are we on developing practical testing that we could make determinations on pathogens, whether salmonella or E. Coli or whatever, and why can't we move quickly. Industry and the government, much more aggressively -- it's apart from -- although it's related to the regulatory questions you're talking about today, I mean the fact of the matter is is that just listening to this indicates to me that -- you know -- obviously technology is part of the answer here but part of that technology is in scientific testing, particularly in an area where the bugs and the bacteria are becoming more virulent, both striking animals as well as people. So we ought to as part of this, the Department needs to take a much more active and aggressive role in this issue of developing

practical modern testing -- the kind of testing that would take place in a plant and I'm going to do my best to see that this moves forward more aggressively than it has before. And, again, this is not in any way on a separate track from the regulatory side of the picture but it does seem to me that -- you know -- people are looking for some degree of predictability here and it does not look like it should take with all the brainpower that we have in this country to take millions of rocket scientists to come with the kind of testing capability in order to provide some predictability for the industry and for the government and for the consumers who want to know what's in the food that's being marketed. So just saying that I just want to say that it's been very useful for me listening to this debate.

MR. BILLY: I think what we'll do is take about a twenty minute break and start again at fifteen after eleven.

(A brief recess was taken)

MR. BILLY: I would like everyone to be seated. Rosemary --

MS. MACKLOW: Me?

MR. BILLY: Rosemary asked a question about video tapes and, in fact, it is being video taped. A tape will be available for viewing here beginning on Monday and you can get in touch with either the desk or I'll give you the information now. Lester Sheppard and the phone number is 720-9113. Copies will be available in a week and for those you can get a hold of Jennifer Callahan and the phone number is 501-7251. There's going to be a sign-up sheet so if you want a copy of the video tape you can just sign up and we'll follow up. In terms of the transcript for these meetings they will be available on October 2nd. They'll be available on disk -- Word Perfect 5.1 -- and, again,

you can get a hold of Jennifer Callahan at the same phone number -- 501-7251. This same information will be out on the table so if you didn't get it or want clarification you can get it that way.

MS. MACKLOW: Thank you, Tom.

MR. BILLY: You're welcome.

MS. MACKLOW: -- -- the video?

MR. BILLY: I guess.

MS. MACKLOW: Should have worn better wear make-up.

MR. BILLY: I think, Mike, you wanted to say something? Maury? Maury?

DR. POTTER: Welcome back from break. I think just to sort of capsulize what we were discussing earlier, our primary goal is prevention of meat and poultry-born disease and I think that everything that we're trying to accomplish here is headed in that direction. The primary measure of that is the incidence of meat and poultry-born disease and we have in place now an inter-agency collaborative food-born disease surveillance program in five sites around the country that's been collaboratively funded and organized by FSIS, SIFSAN, and CDC, to measure the incidence of food-born disease to get a better handle on what the numbers are, what the proportions are, to look at what proportion of these illnesses are attributable to different food commodities so that we can get a fix on where we are and then measure our progress toward prevention of meat and poultry-born disease. This is a very, very big step. It's been long in coming. Epidemiologic data are either qualitative and not very expensive and that's what we've been dealing with or they are quantitative and require a lot of resources, a lot of time and money.

And that's what we're building toward now so that we'll have an accurate measure where we are, where we need to go, and we can measure the progress toward goals in actual reduction of disease associated with products under regulatory control.

The first approximation of that measure is the presence of pathogens on the meat. And we're proposing -- or one of the proposals on the table is to look at that as a measure or progress. That's something that's a little bit easier to measure than incidents of disease and attributable risk factions. And the second approximation is the level of process control of fecal contamination. Most food-born pathogens, most meat and poultry-born pathogens are coming to consumers from micro organisms that were present in feces, either in the GI tract or on the outsides of animals presented for slaughter. So we have -- we have three measures that we can look at to see what kind of position we're in now and how we're heading and I think that we need to keep in mind as we go through the discussions that we're really trying to prevent meat and poultry born disease. Everything points in that direction and we're using all of the measures we can to determine how well we're achieving that goal.

MS. MACKLOW: Mr. Taylor, could -- Mr. Potter, could I ask you a question?

If we wanted to try to assure that every piece of meat or every hot dog going out of a plant or every hamburger patty was safe how many of those would we have to test in order to assure that it's pathogen free, that each of those products were pathogen free?

You talk about maybe a box or a shipment of a hundred thousand pounds of patties which four to the one would be four hundred

thousand patties out of a company and that might not be a total day's production for some of the companies.

Are you a statistician?

DR. POTTER: Pseudo statistician. Pseudo microbiologist. I'm not really here. This is just a hologram.

MS. MACKLOW: You wish it were.

DR. POTTER: In order to be one hundred percent sure that no pathogens were present you would have to test one hundred percent of product and your test would have to be one hundred percent sensitive. So there are barriers to achieving one hundred percent. Around the table everyone has acknowledged that we don't live in a risk-free society and we're -- and while our goal may be the absolute elimination of food-born disease the steps toward that goal are to constantly put downward pressure on the incidents of food-born disease. So we can't through end product testing achieve the one hundred percent safety. We think that through process control we can -- we can get a better indication of the likely level of hazard but as we -- as Glenn said, when we set up a HACCP plan we're setting up a HACCP plan to control the hazard -- the hazard that makes people sick. We're measuring process control by looking at our CCP's and perhaps using some measure of process control like E. Coli testing but at some point someone has to see whether that whole process which is under control is actually controlling the hazard and that's why we want to do some testing for pathogens.

MR. BILLY: Okay. Jim Marsden.

DR. MARSDEN: First of all, this is Jim Marsden from Kansas State University. I'm a little concerned about some of the discussion

we've had this morning about separating the HACCP proposal from pathogen reduction and part of that perhaps is because they are sort of separated out in the proposed regulation. But, remember, the reason that we're all here is because HACCP has been identified as the best system we have to achieve pathogen reduction. That's what HACCP is all about. And the way that HACCP accomplishes that is through the process control that's achieved through the critical control points in the process. Now, microbiological testing clearly plays a role in that but most of what we've talked about relative to microbiological testing has been way downstream in the process -- after the product's already been produced and so on. I think we need to consider the role that microbiological testing should play upstream in the process and that gets back to validating the HACCP plan to make sure that the HACCP plan and the process controls that are inherent in that HACCP plan address the problem of pathogens in the first place. And a good analogy is what we're doing in dried fermented sausage right now. We're working to develop a process that controls E. Coli 015787 in dry sausage and we're not using indicator organisms, we're using E. Coli 015787 to validate the process. It makes all the sense in the world to do that. And once that's done and once we know what the processing parameters are in order to control E. Coli 015787 in dry fermented sausage then all the manufacturers of those products -- large companies, small companies, everybody in the United States and around the world -- know what they need to do in terms of designing their HACCP plan to control that hazard. The same model applies, whether it's fresh meat or processed meats or whatever. We have to develop HACCP plans

that either eliminate or minimize the risk associated with microbiological pathogens. Microbiological testing is a big part of that validation process and in my view should involve pathogen testing in setting up those HACCP plans. Now there's another role that microbiological testing plays and that's in verifying the HACCP plan once it's in operation in the plant. And here's where we're talking about using indicator organisms to verify that the HACCP plan is working the way it's supposed to. And that's appropriate. USDA has identified E. Coli. In some cases that may be the proper indicator organism, maybe totally aerobic plate count. In fact, it's probably the plant product and process specific and it may be better not to prescribe the indicator organism per se or perhaps the motive verification that microbiological testing certainly can play an important role there.

Now, a third place where microbiological testing has played a support role, anyway, is in the baseline tracking that USDA has been doing for the past few years and that provides us valuable information on trends, where the industry as a whole is moving trim-wise. Doesn't single out an individual establishment or put an establishment above or below a mean but rather provides just trim information -- is what we're doing generally working. If we mandate that every establishment in the United States operate under a HACCP plan and then do a proper job of validating those HACCP plans so that we're certain that they address the problem of pathogens then that baseline information should reflect an improvement and I think it has an important role to play and in the fourth thing that we're doing, which is what Dr. Potter referred to is the real measure is how we

influence food-born disease associated with meat and poultry products and I think the agency is doing the right things in cooperation with CDC in setting up programs to monitor the effectiveness of these -- of this major food safety initiative on what really matters and that's controlling food-born disease. So in my view, that's where -- that's where the HACCP system works, that's how it works, and those are the places where microbiological testing play a role.

End product testing, as has been said all morning, is very limited in what it can do. You've just heard Dr. Potter say in order to have a one hundred percent assurance that product is safe we have to virtually test one hundred percent of that product. That's how HACCP was invented in the first place is because that's not practical.

One of the things I think that was said earlier that is probably not right is that the limitation is in the microbiological test. That's really not the limitation. We've made, as a country, tremendous progress over the past years in rapid microbiological testing. USDA has been a leader in that field. Every year at Kansas State University we hold a workshop on rapid microbiological testing and it sells out every year. There's a tremendous amount of interest. There's high tech companies all over the United States and around the world that are developing better and better methods all the time. That's not the limitation. The limitation is in the sampling. You cannot sample everything and have everything left over to consumer's food. So end product testing has limitations that we'll never be able to address. We'll never be able to get a handle on food safety by relying on end product testing.

A good analogy that I've used many times is pasteurized milk. The effort was put up front in developing a system to control pathogens in raw milk. And it does that beautifully when it's done properly. And that's where pathogen testing and everything else plays an appropriate role in setting up that process in the first place and then it can be verified periodically either with microbiological testing or in some cases even enzyme testing or something just to demonstrate that the product, if it's a heat treatment, has been heated to the proper temperature.

So the vision that I see of HACCP and the role of microbiological testing is that we set up a process that can be demonstrated to control pathogens, verify that process, usually with microbiological testing, conduct microbiological trend analysis which would be, in my view, an agency responsibility, and then evaluate the overall impact through the on-going surveillance of food-born disease associated with meat and poultry products. Thank you.

MR. BILLY: I want to -- thanks. If you look back at the agenda in terms of A and B and establishing performance standards we've had a good discussion on the first billet -- the scientific and policy basis for establishing targets. The next three billets really deal with which species, which organisms, whether salmonella is the appropriate organism for some or all species, whether other pathogens would be preferable for some or all species, and the utility of targets for E. Coli or other non-pathogenic indicator organisms.

What I'd like to do is encourage more discussion on those areas in terms of keeping -- make sure we cover the agenda we agreed to and open it up for comment in that regard.

Jim?

MR. LOCHNER: Jim Lochner at IBP. My comments do pertain to those and it really started back, I guess, initially when my comment was formulated when Gary Acuff was talking.

I think first any discussion we have on microbial monitoring everybody better clarify whether we're talking about fresh or cooked processed product. And I'd recommend to you, Tom Billy, that they don't ask. My comments are going to be directed at fresh because we're talking about two totally different concepts in the system. What I want to talk about a little bit is, I think to sincerely improve the process you have to have some blind faith. And that is, we have to have an indicator organism, be in either E. Coli species or fecal coliforms and it may not correlate numerically worth a darn to pathogens but we know that it correlates at least positively to the source of pathogens specifically enteric pathogens. Now I know it does not correlate at all to the non-enteric pathogens. So listeria and staph, I know it's not a very good relationship, but it is to salmonella, pathogenic E. Coli, and campilobacter.

I know a number of people play golf in here. I do play golf. Does anybody not keep score other than my wife? The reason people keep score is they want to monitor their progress. You cannot have an effective HACCP program and talk about bacterial monitoring and the finished product unless you are keeping score. Now, I think the real issue's going to be what level. That's going to be the dilemma indicator organisms. And I could force all this discussion on very quickly and say what level are you thinking about? I'm going to revert back to the fact that the roster isn't cleaned up yet so we could

divert our attention. I think what we have to do and the agency has to do is really determine how are we going to monitor progress using indicator organisms and pathogens and that's what you're wrestling with. But I don't think we should debate whether E. Coli or fecal coliforms is a matter of source of enteric pathogens because I think it's fairly well understood that it is and I think it's fairly well understood when you make progress you've got to monitor yourself and you've got to get over those two principles and assume to some degree, if possible, that we have to have those things to make progress cause if we're sincerely, and I believe everybody genuinely wants progress, let's get after eliminating the source and figure out where the process change, not accommodate process changes that exist today that encourage or allow for cross-contamination. We cannot have massive dichotomy between various products because the systems today allow for it. We have to go after changing them.

When zero tolerance is implemented in beef we should have had zero tolerance in fecal. There's a concept that's a little difficult. But we knew the source was there so we choose processes. We tried to eliminate to the extent technically possible and I'm going to tell you, E. Coli numbers dropped -- generic E. Coli or fecal coliforms -- they improved. Logically they should have. To what degree in across the industry it's a bit difficult but I can tell you internal numbers improved. Now, theoretically, I can't tell you to what extent we reduced the probability of salmonella but I know it had to improve somewhat and I think that's where we got to quit getting hung up on debating how much. We can get trend lines. We all grew up pretty much in the system that operated on where you stood -- hundred

percentile -- at least I was graded many times on what percentile, be it either when you went through the fitness exams or you went through grades, so percentile grading is a concept that could be used. Data accumulation to know where an establishment stands on a percentile maybe for a year or two so that it will be self-motivated. Nobody's going to want to be in the twenty fifth or bottom twenty fifth percentile. You best be looking at your process or where are you failing if you're there. The problem is we have no -- and I don't believe we need a standard -- we need to know what is the norm, what is the median, and then we can judge our own processes from there. At some point, however, if you're not so inclined to do it basis or self-motivated change your process then there may be some regulatory necessity to come in for enforcement. Therein lies the issue. So those are some abstract thoughts to think about.

The fresh meat is difficult. It's going to take trend lines. The other thing is all the data generated thus far did not look at the calendar year and I appreciate that we should be able to do it consistently but you need to know that so that your reacting. And over a year or two's period if we got good information and comparative data we should be able to make progress but we, again, cannot accommodate processes that don't deliver and it's going to take some time to change the process. The goal's got to be to get rid of processes that don't deliver pathogen reduction in fresh meat.

MR. BILLY: Okay. Mike?

MR. ROBACH: Thank you, Tom. I'm Mike Robach with Continental Grain Company and I'm here today on behalf of the National Broiler Council as well. I think one of the basic premises of the meeting

today and the meetings that were held earlier in the year was the idea of what role microbiological testing and performance indicators have on this whole process. And very clearly micro testing gives us an objective measurement of performance. I think everybody agrees with that. And micro testing clearly has a role in the verification of a process, especially a process where we're looking at destroying micro organisms in a fully cooked operation and I think you can talk about standards when you talk about a fully cooked operation. However, when you're talking about a raw operation I think you have to look at the use of guidelines and these guidelines are going to vary by season, by flock, or herd and that needs to be understood.

One of the other points that was brought up this morning was of a whole aspect of testing but the testing technology was holding us back. I don't believe any amount of testing can make pathogens go away. Controlling one's process is the way to reduce pathogens. And I think most of us in the industry certainly understand that clearly day in and day out. So the proposal in the issue paper that the agency delivered today I think meets some of the requirements that we feel are necessary in the industry. We believe the use of E. Coli has an indicator organism to verify process control is an appropriate use of technology. I don't believe that looking at the incidence of salmonella is an appropriate use of technology to verify process control in a raw plant. It certainly isn't there. The process is not capable of producing a pathogen free product. Just can't do it. So quantitating E. Coli is much more effective than a qualitative analysis of salmonella when it comes to process control.

In terms of pathogen reduction, there are not perfect

correlations between E. Coli and salmonella. However, there are strong indications that if you reduce E. Coli you are reducing fecal oriented organisms. Therefore, you are doing what needs to be done to improve the microbiological quality of raw product. E. Coli fits very well into the verification process. You get a fairly rapid turnaround. When you see numbers you know something's happening in the process. You have the ability to go back and take appropriate corrective action. You will, through the course of applying this type of analysis, be able to reduce your enteric pathogens.

The critical limits that we've talked about or have been mentioned regarding E. Coli levels or other indicator organisms -- what levels -- have to be looked at very carefully because they are going to vary between species and they are certainly going to vary based on process capability. We have to make sure that we understand what the capability of the technology is in our operations today before we get too far down the road to setting guidelines.

Again, I believe that the use of microbiological testing as laid out in the issue paper today as an appropriate use in that technology. And it is the way for us to move forward. We have debated this time and time again and I think we've come to a general consensus that using an indicator organism for process control verification is appropriate. The agency has indicated that they're interested in going and looking at salmonella on a compliance level to make sure that they're meeting targets that they've established. I think that's fine. I think the FSIS wants to do that. That's something that they should move forward with. The industry will go ahead and use E. Coli as a verification tool for our process. And I think if we can come to an

agreement on that then we can take the next step and start discussing the details of the implementation and final drafting of such an agreement.

MS. DONLEY: I just have a general question just for clarification that might help a little bit with my mind in this discussion.

As far as for the process control or Dr. Morris -- where would -- where would -- is there any one point -- is at the end of the process that the samples would be done or do you have any views on that or is it going to be done several times within the process at different critical control points or is it the one time?

DR. MORRIS: That's the sixty four thousand dollar question. I think --

MS. DONLEY: I thought it was simple.

DR. MORRIS: I think the thing to say is, again, conceptually that the E. Coli testing would be an element of process control and, again, now let me emphasize that personally I would see that -- you know -- in the future that this -- that the plants as part of their HACCP plan would incorporate E. Coli testing in potentially different spots, potentially multiple spots along the line but whatever their HACCP plan indicated that it was appropriate or necessary. What we are talking about though is more immediate, short-term interim measures to begin to really open up the HACCP era and I think the specifics there are still not that well laid out.

MR. BILLY: Pat Stolfa has the --

MS. STOLFA: At the risk of further demonstrating that the specifics are not that well laid out particularly among us and to let you know that indeed we are coming to you with our most current and

our best thinking to this time. It's a way to think about using generic E. Coli is to think about it as a performance standard and it seems to me that as a performance standard there's some utility in trying to pick a point at which we already have some data and so we might look to our baseline surveys and the points at which we took samples in our baseline surveys to see if those are appropriate points to impose a performance standard, particularly since we took in the raw product areas we took those samples relatively close to the end of the process and so close to the time when the product was either moving into further processing or leaving the control of the slaughtering establishment, certainly in the case of the steer, heifer, and cow bull line and broiler so the kind of though that occurs to us if we consider this as a performance standard is that we might have sufficient baseline data from those surveys which were large sample long-term surveys that we could arrive at a reasonable approximation of a performance standard and have some basis for doing that that relied on data that we had developed and had developed in recent past.

MS. MACKLOW: Could I just ask Pat -- do you have that data handy here today for us all to look at once again?

MS. STOLFA: We might speak informally about some of it but I think maybe Ann Marie and Rich would be -- would you like to speak a little bit about what we've got on the E. Coli?

MS. MACKLOW: This was published as part of the baseline data wasn't it?

MS. STOLFA: Yeah.

MR. TAYLOR: Let me make just an overview observation of what one of our objectives is for today's discussion and -- I mean you're

getting to one of our objectives here which is we got a lot of comments, we had scientific conferences that said generic E. Coli is the more effective indicator organism for fecal contamination and one of our objectives in light of the enteric pathogens commonly present in fecal matter is to have an indicator organism for fecal contamination. We got around this table and in this room some of the world's leading experts on process control, microbiology. We would like your thoughts on very specific issues like if it's going to be, and obviously we're not at the end of the decision making, but if it's going to be a generic E. Coli process control indicator for fecal contamination we'd like input about what this quantitative standard should be, where the samples should be taken, and if there are folks -- experts -- sitting around this table who have ideas about that we would ask that you provide them. I mean I -- it's very important, at least, to get the maximum value out of this from our standpoint, that people not hold back their specific thoughts. We are going to keep the comment period open for some brief period following this meeting so those specific thoughts -- you know -- can be developed and submitted later, that's fine, but I'd like us to focus increasingly as we go along on some of the specifics as opposed to some of the conceptual issues on which I think, if there's not unanimity in the room, there's reasonable wide agreement and we've had a good discussion about it anyway -- like the fact that you can't achieve food safety goals just with testing or just with process control. Our thinking is you have to do both. I mean I think we've had that discussion. I just want to encourage as much specificity as possible on these key issues. We don't pretend to have those answers but there

are issues we know we need to address.

MR. CARNEVAK: Let me comment on Pat's remark about the data from the surveys. As you know we've been in the process of conducting a number of raw product surveys over the last several years. The only one that is available now as a final report and many have you have seen that is the steer/heifer survey. We have recently completed a cow/bull survey. We're close to completing, I believe, a broiler chicken survey and we've got some other surveys under consideration.

If you look at the steer/heifer data, we did look at six pathogens as well as three indicator organisms and we looked at a range of E. Coli, biotype 1 concentrations in the samples that were positive for E. Coli. So if one would scan that range they would see the averages that we arrived at for different levels of E. Coli biotype 1 in the samples that were positive. From that data we would look at that data and try to determine what a reasonable level might be for establishing a -- I wouldn't want to use the word critical limit -- but for establishing a performance standard for a reasonable E. Coli concentration that would be indicative of good process control or good fecal control contamination. So that would be the kind of data we would look at. If you look at the steer/heifer data and the specific enumeration information on E. Coli biotype 1 you would see the kind of information we would be considering in establishing performance standards.

The other raw product species survey should be available hopefully -- I'll let Ann Marie comment on maybe the availability -- I know we're very close with cow/bull. I'm not sure of the exact

timing on the others.

MS. MCNAMARA: Like everything, with so many initiatives, some things get pushed back and the statistical division and the micro division are working very diligently to try to get these reports out to everyone. We would make them available as soon as they become -- we'll make them available to you as soon as possible and that's one of our major goals. So in the next few months you should be seeing these coming out.

Let me also say that these nationwide studies also address some of the concerns some of you around the table have had about having year long studies that take into account the seasonality that occurs in data gathering and in levels of micro organisms that may be seen. So this was also one of the reasons why we chose the baseline studies as maybe being the most appropriate data that we have at this time to set some performance criteria.

MR. BILLY: Barry?

MR. MARSHALL: Thank you, Mr. Chairman. First of all, there's a lot of good discussion here today and I just really want to put New Zealand's position on the table and also for a few things into head that may be helpful. I'd like to say that right at this point of time that New Zealand certainly endorses the overall strategy of FSIS to improve their safety of meat products and to limit the levels of fecal contamination entering the food chain. I mean this was the thing that we all wanted to do even in New Zealand.

New Zealand is a country that is totally committed to this philosophy of HACCP and we'll continue to develop scientific basis for and the implementation of validated process control.

Now, there's a lot of discussion here earlier on about what organisms should be looked at, what shouldn't, etc., but I think what we need to take into account is it has been mentioned by one or two individuals that the whole aim is to reduce the risk. There's no such thing as zero risk. Unless we accept that then we're not going to get too far. And it was clearly pointed out by a previous speaker that unless you do a hundred percent testing of a hundred percent of product you're never going to be sure that the product you eat is going to be totally free of whatever you're looking for. So the whole thing is geared up to what sort of issues or organisms should we be looking at and what shouldn't we be. Before I sort of give you the New Zealand perspective I think we've got to put into perspective the fact that microbiological testing is only part and parcel of the whole spectrum of what we're trying to achieve. It's not an end result in itself and microbiological testing by itself won't give you the certainty effect that you want. There's a whole range of things and we've put a pretty substantial submission into FSIS but it really starts on the farm. You need clean -- unless you have clean stock coming in for slaughter you got a problem immediately. The moment you cut your -- take the hide off you're going to -- while the skin -- while the flesh under the hide is sterile, the moment the hide comes off you get aerosol then you're going to get a bacterial floor on the -- immediately. And what happens as a result of the handling of that product is going to dictate what the outcome is at the end. So the whole trick is to make sure you have hygienic dressing practices, standard operating procedures, all the good things that FSIS is proposing. We totally support it.

One of the key issues in the thing is the cold chain. The moment you know that a carcass has been eviscerated and inspected that they should go into an environment where the temperature of the product is decreasing and then it should be maintained at that temperature right throughout the processing, whether it be cutting and packaging, transport, delivery to the consumer at the other end. We've been doing this for the last twenty odd -- twenty five years since the early 70's. We had a cold chain in place with standards with having to meet a whole range of other things and perhaps that's one of the reasons we have been exposed to some of the unfortunate things that have happened in this country. But as a major exporting country, we've just got to get it right. We don't want our consumers, whether they be yourselves or our local domestic population, being put at risk so we've taken the initiative here.

I'd like to get on to a few of the things about what we should be looking for and what we shouldn't. In New Zealand the aerobic plate count, which is just a measure of the -- I'm sorry -- the aerobic bacteria that's on the carcass that results once the hide comes off -- that's been the centerpiece of the New Zealand program and the New Zealand meat industry's thrust and microbiological testing and monitoring and control procedures for the last twenty five or twenty to twenty five years. We've used amine aerobic plate counts or APC's incubated at the usual temperature, etc. as the indicator of choice for general cleanliness and hygiene of the carcass. And we've found that these APC's provide a continuous measure of microbiological contamination from which the industry can take action and identify whether we actually have the system under control or not. Now, the

value of the APC's as a general indicator of contamination really can't be underestimated. From the general feeling here, it's not going to get -- -- but I'm making the point here just to say you know where we feel. Several of such projects have been carried out in New Zealand and we have done this on sheep dressing, for example, and we used -- well, as a classic correlation between aerobic plate counts and E. Coli -- that's generic E. Coli levels. And we've used that to identify critical control points in addressing system of a protective species of animal and this was, in our case, was sheep. And we looked at the whole process from the moment the animals came on to the slaughter board, got slaughtered, right through to when they left the slaughter board and really at the end of the day there was only one critical control point. It really didn't matter whether people were -- you know -- well, while one expects people to have good manufacturing practice or procedures -- wash your hands and keep clean and sterilize their knives when they became contaminated -- at the end of the day those had very little effect at all on the end product. What really -- in the case of New Zealand and sheep was that it hinged on the length of the wool. If the sheep came into the yards -- and of course we wash everything before we go -- but if they were -- had long wool or dirty and are wet then we -- that's when we get the very high contamination levels on the carcass once the fleece came off. If the short wool dried and cleaned we had a very low baseline. So in this respect APC's have been quite effective for New Zealand in actually determining the whole range of things there.

In terms of enteric bacteria, they can often be limited as indicated as a process -- hygiene -- due to the wide diversity of

where it may be located or the -- -- of the distribution on the carcass. They're not all evenly spread out all over the carcass and, therefore, the counts in these bacteria and what have you frequently drop below the limits of quantitative assessment so it's -- you know -- a problem occurs there.

Now, we all know there's a lot of people here that are not scientists and so I'm just going to make this so that they understand because there's a lot of expectations from the private sector which really, I think, are worthwhile but I think they are a little bit unrealistic in what they're expecting.

A good bacterial indicator of enteric pathogens -- in other words, pathogens that come from the gut are going to meet a number of important criteria. They got to be specific to the intestine so obviously if they're -- you know -- enteric pathogens really to be detected they've got to be present in high numbers in the feces. They've got to be easily reliably detected when present in low numbers. And they should have a die off rate parallels the pathogen of concern. Now, the role of thrust here is for FSIS is towards salmonella, the hope is that by targeting salmonella and by marking out all the other pathogens that we haven't even considered here today, so what we'd like -- well, our evidence from New Zealand -- certainly all the data in the literature states that salmonella doesn't actually satisfy all these criteria. And usually what happens -- it can actually be carried -- well, generally, it's recovered in meat in low numbers but you've got to use specific isolation procedures which are complex and therefore more expensive for testing purposes than perhaps some of the other indicators that can be used probably more

effectively. Furthermore, many of the tests that have been put forward or suggested for salmonella really just doesn't enumerate the number of organisms whether they're present or absent. Now, that's a problem in its own right because not only -- well, you might have E. Coli 015787 which might have an infective dose of -- -- organisms per gram of product, with salmonella, depending on the species, it may be a million organisms per gram so this is the problem. If just the presence or not of salmonella is not an indication of just what is the level of contamination. All you know is it's there but you don't know to what degree it's there and this sort of thing.

We found that in New Zealand, anyhow, and I'm pretty sure it's in this country, that salmonella species in the live animal -- the presence of it is sporadic. It's not there all the time. As I mentioned before, it's only apparently one percent in this country, significantly less than New Zealand, less than .1 of a percent. And so for us to test the salmonella at that level as one of the previous speakers said -- I jotted it down here somewhere -- that -- I can't even find it now -- anyhow -- to test for -- you know -- to test for negatives is a nonsense situation. And certainly as far as New Zealand, we would actually be going down that trail.

So the problem is because of this small amounts or sporadic incidence or prevalence of salmonella in live animals and consequently the fecal contamination on the carcass not being homogenous, not being covered over the whole carcass but being sporadic here and there, and the distribution of salmonella between carcasses differing, we feel that perhaps we're sure that salmonella,

as far as New Zealand is concerned, is certainly not the organism of choice.

One of the things we actually did a bit of steps on the prevalence that FSIS has said was salmonella prevalence -- the one percent and I'm not quite sure why -- whether that was the actual prevalence or that was close to it or what -- but there's a one percent, using the one percent that's being suggested in all these other systems that are put in place that are being considered such as the moving some sampling plan and this sort of thing we see it as actually not being appropriate for the New Zealand condition simply because it's very slow to -- slow response time to determine what acceptable one -- what acceptable -- what -- and you actually get unacceptable failure rates for acceptable production. So we noted that there was actually a twenty percent chance of failing acceptable product over an eighty three day period based on what's been proposed and a sixty one percent chance of failing acceptable product over a two hundred sixty day killing season. This is almost nine times as many -- so really to get the confidence you want because of this -- between salmonella and something like E. Coli -- you actually will need nine times many more samples needed to actually detect a doubling of rate of contamination of salmonella with a prevalence of one percent if it's used as an indicator. Then with E. Coli -- with an incidence of eight percent. So what I'm saying here is that it's -- well, much better to look at something as been suggested from a number of the speakers that perhaps E. Coli's the way to go. And what's so -- New Zealand would like to propose -- in fact we have in our submission -- that E. Coli is actually the more suitable indicator

of contamination by fecal bacteria and that it actually better satisfies the criteria for an indicator organism and salmonellas -- you know -- just doesn't do that. There's quite extensive data relating to growth rates, death rates, to temperature for both E. Coli and salmonella and there's reliable predictions that can actually be made for potential growth rates, etc.

But to wrap it up I'd just like to say that New Zealand's totally behind what FSIS is doing. We want to get to the same end point. Perhaps we'll disagree pretty vigorously on perhaps how we get there but we want to insure that the public and New Zealand as well as other countries we supply are certainly not at risk from any pathogens. Thank you.

MR. BILLY: Gary?

MR. WEBER: Gary Weber with the National Cattlemen's Association. And, Tom, it's been a while since I asked you if I could talk. There's so much that's been covered and that's not -- I think that's great. A lot of people are getting their thoughts in but since I asked to speak, a number of points have been raised which were similar to the points I was going to make so I'll be very, very brief.

But, first and foremost, I want to make a statement that as the producers of the products we're very concerned about this entire issue, not only what we're doing on our farms and ranches, but what occurs in the plants and what happens in transportation and what happens in the retail stores and what happens in the household because all those must be thought of as part of the system and we will do our part to help insure the safety of the food supply.

As we look at the proposal that FSIS has put forward in your

issue statement that was released yesterday, I want to applaud your -- as Pat Stolfa said, it is indeed, perhaps from my point of view, the best thinking that I've seen coming out of FSIS here on this issue. It's excellent. It's on the right track. Certainly, the devil's in the details and you need to work through that with the industry that has the data on generic E. Coli and how to being establishing the appropriate guidelines or targets, etc. With respect to salmonella and other pathogens, we would be very disturbed if as the process of putting HACCP in place we do not see, based on trend line analysis, very significant improvement over time in fresh product of the presence of those pathogens, and, consequently, are very supportive of the concept of using the baseline studies for salmonella or other pathogens to document this improvement over time. And we will certainly be immediately at the table of FSIS and at other locations if indeed it looks like we're not improving we're going to be asking why and want some action taken to see that we're making progress. So I want to reiterate support for the movement toward E. Coli. I think that's certainly going to be helpful and we'll work within the HACCP system as a result of our discussions with a number of scientists and industry. We're not adverse to looking at salmonella and other pathogens from the standpoint of baseline studies. Those are very effective. But we also want to ask the last point is, as has been stated before, that FSIS be very honest with everyone -- that this is a long process of improvement. We can't guarantee that the product leaving -- if handled improperly will not put someone at risk and so we need that strong communication from the Department that there is indeed responsibility to all steps and I promise everyone here we'll

take our -- our responsibility seriously and do what we can to do our part in this. Thank you.

MR. BILLY: Mike.

MR. TAYLOR: May I just be at a point and then make a request. First of all, I appreciate your comments, Gary. The issue of -- when you said we need to work with the industry which has the data on generic E. Coli -- in order to set this quantitative standard, I think I understood you correctly, we would agree with that and we have data from our baseline survey. Our administrative record will be open for thirty days following the close of these meetings and I mean I invite, urge, encourage, request those at industry who have data relating to the decisions that you know we're looking on to please submit it and this needn't be plant specific in terms of identifying the particular plant. It can be in the data that are aggregated by your organization or others but any data that the industry has that would enable us to make the best possible science-based decision we would request that you submit the rule making record and I guess I would say the same thing. We do intend to use the data that we have available to us, including the baselines, in the event -- I mean we reach a final decision to adopt targets for pathogen reduction but I would make the same request to industry with respect to data that it has. We made this request in the February proposal, frankly, to no avail. We'll make the request again if industry has a way to aggregate data that is in its possession that would permit us to have the best possible understanding of current incidents of contamination as well as quantitative levels -- whatever data you have -- of raw meat and poultry products with pathogens, we invite that. And, again, it

needn't be plant specific or company specific but aggregated data because if we're going to make good on achieving the objectives we're talking about and if we choose to use the kinds of performance standard tools that we've been discussing, we obviously want to base these on the best available data and we'll work with what we have but if you can prove the quality of the data, the quantity of the data that we have to rely on, we'd really appreciate it.

On your final remark about we need to be honest, that this is a long process of improvement, and that it is unlikely that we're ever going to be in a mode whereby product coming out of a slaughter plant can be subject to abuse and still not pose a public health or food safety concern, I agree with you completely. What we do believe -- what's invited in the proposals is the notion that there is substantial room for progress in reducing pathogens and reducing incidents of contamination of raw meat and poultry products with pathogens and that in so doing, by reducing the incidence of contamination with pathogens we reduce the risk that consumers ultimately bear that through abuse at whatever point a food safety problem will result. But it's not a zero risk enterprise. Nothing we're doing is by itself a silver bullet but we do think that through a long process of improvement that we can make substantial progress in reducing risk. That's the objective. We'd like -- everybody would like a hundred percent elimination of food-born illness and -- and that's an aspiration that probably all of us have at a personal level. We know we have to work hard to achieve reduction and we need to get a system on a path to do that. So I mean I agree with your observation there.

MR. BILLY: Carol?

MS. FOREMAN: A question please. For those plants that can indicate a level of quality in terms of E. Coli that is substantially above that the industry meeting it will they be able to make a -- I'm sorry -- Carol Tucker Foreman again. Just in case it wasn't done, for those plants that are able to regularly produce a product that is far above the industry median -- those who are in the top five percent -- ten percent -- will they be able to make a label claim that they are in fact far above the USDA requirements so that there is an incentive?

MR. TAYLOR: That's an interesting important policy question. It would raise a lot of, obviously, specific issues about what would be -- you know -- how that would be done appropriately and I, either at today's meeting or in subsequent phase of a reopened comment period, welcome specific thoughts. I mean the idea that through market incentives, in effect, -- you know -- improvements can be brought about in the safety of food products -- I mean in reality that's going on right now, not through the use of label claims but because as one -- the president of one poultry operation told me, his customers tell him that they don't want bugs on the products so he's getting the bugs off the products and so there's a market -- demand -- you know -- to improve food safety. A lot of complex issues about how you use affirmative label claims without misleading and so forth.

MS. FOREMAN: I understand but as long as -- I continue to be troubled about the presence of the USDA inspection seal on all this fresh product that some of which falls below the industry median so that it turns out that the seal represents the minimum level of achievement with regard to food safety and if it remains as the

indication of a minimum level of achievement I do think there is a market incentive to having something that says we go above that. We are better. And I believe that kind of market incentive might very well pull other segments of the industry ahead faster than a government salmonella testing program and once again should enhance process control in a way that enhances food safety. So we probably will get you some comments on that.

MR. BILLY: Carol? Carol? On September 29th the item B, incentive based alternatives such as market claims and labels --

MS. FOREMAN: Oh, I'm sorry. Terrific.

MR. BILLY: There's a -- which I think you suggested at the grouping session. You set the stage for that discussion and we will address this area -- you know --

MS. FOREMAN: I should be here to hear the arguments against it.

MR. TAYLOR: Really, my desire for as much specificity on all sides of the discussion as possible. There's a concept there and then there are also a number of specific issues about how you would do something like that and the more we can -- everybody who wants to participate in that on that issue can get the specifics -- pros and cons and so forth. I mean that's what would help us -- you know -- grapple with that issue.

MS. MACKLOW: Could I just speak to Carol's point for one moment please?

MR. BILLY: Sure.

MS. MACKLOW: Maybe when we can come to that September date Carol would be able to bring us back some information on the value that's putting the TQC symbol on processed product has had. That was

something that she initiated during her term as Assistant Secretary and we've now got nearly about fifteen years experience on some of that and that might be very useful.

MS. FOREMAN: Unfortunately it happened just as I left so we really weren't able to pursue it the way I wanted.

MR. BILLY: Joe?

MR. PEMBROKE: Joe Pembroke with Kraft Foods. We had a number of issues raised and I think at least we had them put on the table. Mr. Hibbert, on the authority, a cogent argument that has to be addressed, and I think we also had Mr. Lochner -- how much and what level. And a third issue that I would like to raise is if these levels -- the baseline levels are exceeded what action does the agency plan taking?

DR. MORRIS: Again, I think this is one of these issues where we would welcome suggestions. I can tell you that one conceptual framework would be that if one regards the pathogen targets as an indicator of the effectiveness of the HACCP plan then a failure to meet a pathogen target would indicate that there were problems with the HACCP plan and so there would have to be a re-evaluation of the hazard analysis and of the HACCP plan. Again, it's not envisioned that this would result in -- you know -- a lot of product being locked up. But this is not what this is. This is a means of validating a HACCP plan. I think, again, as apparent from the discussion this morning, in terms of E. Coli testing, again, there, we would see that more as a process control indicator, and, again, the way in which that information would be used is something where we need suggestions or ideas. Again, one conceptual framework would be to see it as part

of the overall process control system within the plant and so -- and, again, keep in mind that you're hearing differences here and what we want is input as to ways to approach this. One conceptual framework would be to see it as a critical limit which would be handled in the way that critical limits are handled as part of the HACCP plan. Another approach would be what Mr. Billy was indicating earlier. I think what we need is input of the appropriate ways in which deviations from these targets, standards, guidelines, might be handled. But as I said, I think the overall concept is, again, we're not going to stop the product at the door. We're going to use it as a means of looking at the process control or looking at the HACCP plan.

MS. DONLEY: Thanks for asking that question. I think what I was trying to ask a long time ago in a very poor way. When will product get stopped at the door?

DR. MORRIS: I think when there is a breakdown of the process control system. And, again, I think these are -- these are the issues we've got to come to grips with.

MR. OLSSON: Phil Olsson here with International Meat Association. Let me follow up on Joe Pembroke's question because I think that earlier today we had something that from your side was described as a significant change from what is in the proposal as different conceptual framework. There's been a lot of thinking and a lot of new thought that's come forward and that's all very good. But I think that in connection with that where there are questions such as Joe has posed about what is the consequence of exceeding the levels, Dr. Morris, I don't think that we can both pose those questions and answer them. I mean if this is a new conceptual framework and we

are here in the spirit of give and take which is the -- I think the premise for these meetings and we are here with the understanding that we're here for dialogue, not delay, and that the agency has a December 31 deadline to get things done here and to get things activated, we really need to know when Mr. Pembroke asks -- you know -- what have got in mind in this conceptual framework. We need to really have this exchange and this detail and -- you know -- I should not take up the time while there are so many distinguished microbiologists around this table because I understand you want their input but I do think we need the exchange.

MR. TAYLOR: Let me just -- on that particular issue let me just repeat what I said this morning on that which is what our current thinking is with respect to the consequence of a finding that a plant's process control was not achieving the target for pathogen reduction. What we envision is the consequence of that is that we would through compliance, oversight, and further inspectual activity, hold the plant accountable for making the necessary corrections in the process control system to achieve the target. And a plant's inability to do that at some point would result in our not allowing the plant to continue to operate which is precisely the concept that was laid out in the proposal with respect to the consequence of not meeting the target under the proposal. The distinction is that rather than requiring, again, as we proposed the plant to do the testing that leads to the finding, the target is not met, really the difference here is simply that we would be taking responsibility for doing the testing to determine that the -- whether the target was met. And so -- and so let's -- and so there's no kind of lack of clarity in terms -- and,

indeed, really that issue of what's the consequences is not a departure from the proposal and let's talk about it. I mean it is a tool. As the paper says, what we're looking for is a measure of accountability for controlling and reducing harmful bacteria. It's a pathogen reduction performance standard that is meant to be a tool of accountability which means if you don't meet the standard it is our responsibility -- it would be our responsibility as the regulatory oversight agency to see that you do. And that's the idea. And so I mean I agree with you. We ought to before it goes over have a focus discussion -- is that the right consequences or not. I mean let's have that conversation.

MR. HIBBERT: Could I make a comment on the specific question? If I understand this discussion correctly the -- this is Bob Hibbert again for the record -- the failing to meet a target -- let's assume -- let's assume we're in a system where the Department generated E. Coli testing and there is some above --

MR. TAYLOR: That's not what we're talking about.

MR. HIBBERT: And so I may have been missing the point. This is the pathogen reduction testing which is now going to be done --

DR. MORRIS: Salmonella pathogen.

MR. HIBBERT: Excuse me. Salmonella -- excuse me -- done by the Department is a process verification tool.

DR. MORRIS: Pathogen target.

MR. HIBBERT: Target. Right. Now it seems logical to assume that a high level might create some special scrutiny or some skepticism about the operations of the HACCP plan and that seems reasonable. We've got a high number here. What do we do about it?

However, going back to kind of the hypothetical I was offering earlier, it would seem that at least one possible conclusion you might draw after you look at the HACCP plan is that nothing is wrong with it. I think that might or might not happen in a given circumstance. All I'm suggesting is that the Department under the scheme of things would keep its mind open that while that test is a trigger, a yellow light goes off, we need to look at this more carefully, you might then look at the plant carefully and come to the conclusion that it was operating at perfectly acceptable HACCP plan.

MR. TAYLOR: What I hear you saying, Bob, and correct me, is that when we are actually in a compliance mode based upon the kind of analytical results that say the target is not being met, the appropriate regulatory response could vary with the circumstances is what I hear you saying. Well, of course. I mean -- and we -- we can try to think ahead and envision an array of hypotheticals and try to anticipate how we might react but the principal that as a regulatory agency holding a plant accountable for meeting a regulatory standard -- you know -- the principal that our -- the appropriate regulatory and enforcement response will vary under the circumstances, I mean that's -- that's a principal that is unavoidable. The objective though is to effectively, meaningfully, hold the plant accountable for process control to meet an appropriate standard of food safety performance with respect to pathogen reduction.

MR. HIBBERT: Just one more comment. I wouldn't quarrel with that. I guess the distinction here that I think is important is at least as I read the proposal the Department seemed to be saying in its proposal that -- that an above baseline test result would

automatically lead to a conclusion that there was a problem with the process and all I'm suggesting is that that might not be the case in every circumstance and to the extent the Department is open to that possibility I think that's progress.

MS. FOREMAN; I have -- this is Carol Tucker Foreman again. I have the flip side of that. Is there going to be a number at which the Department would decide that that product that you tested was constituted an adulterated product?

MR. TAYLOR: I think that's a very important question and it goes to Nancy's concern because in what the data tell us about salmonella contamination in -- -- carcasses, for example, is that there is a high percent incidence. Generally speaking, the numbers are low. The reason presumably, therefore, that we have a significant number of cases of salmonellosis in the United States is due in part to product handling consequently. I mean that's a reality. One of our objectives, again, of this initiative is to reduce incidents and therefore reduce the risk that occurs from subsequent product handling and mishandling.

On the other hand, if we were to find through our testing that not only is a particular lot positive but has unusually high levels in light of what we know both about -- -- incidents and also high levels in light of what would pose a public health concern then you may have a situation in which at some level we would judge that that product is unfit for food and safe and we would have to come up with a legal theory, no doubt, to satisfy Bob, but certainly you cannot exclude the possibility that at some level -- quantitative level of salmonella contamination you have a product that should not be in commerce so -

- and what we don't know scientifically we don't have any rule and a science-based sort of ability yet to say here's the magic number of salmonella organisms. We'd like to know that. I mean we've foreshadowed in our February document, I mean, an attempt to look at that but --

#3 MS. FOREMAN: Just one final point on that again. If you could begin looking at -- there is a wealth of studies on this subject of what might be the dose response on salmonella. It's my understanding that they start at one level and they run out at another level. There's a range that most of those studies seem to fall in. Is there enough -- I ask you -- are there enough data that you could begin to determine a range where you have a human health problem?

DR. MORRIS: I'll let Maury answer that in a minute but let me say also, I think, again, this gets back to the concept that we will establish initial pathogen targets but this is not a -- this is the way we're going to do it for the next fifty years system but I think there has to be a recognition that science is dynamic, our understanding is dynamic, industry technology is dynamic, they must change and I'm not sure there are the data that are adequate at the present point in time to do what you're asking, but at the same time, I would hope that five years from now there are those data and I think we need to see this as a dynamic process. Our goal is to improve food safety. It's not just we're doing this now and we're going to forget about it forever. This is an on-going dynamic process.

MS. FOREMAN: What's the incentive under the system that we're thinking about to improve that data?

MR. BILLY: Yes. An earlier question are there adequate data.

You want Maury to -- go for it, Maury. Jim Hodges and Joe have comments on that. Maury, you want to go first?

DR. POTTER: We need to try to address Carol's question. We have better data right now for some organisms than others. We have reasonable data to construct dose response curve for shigella. Shigella is more often person to person than food-born but we do have some -- some data points through which we can draw a line to predict the proportion of people exposed at different levels that would become ill. There are a lot of data for salmonella. The data unfortunately contradict each other and it makes it a little more difficult to interpret. There are all sorts of pathogen host and food influences on response to various doses that complicates the issue. I think Glenn is correct though. Over the next five years -- five not years not being a magic number but it's some indication of near term rather than lifetime sort of generational data that we should be able to construct at least rough dose response curves for quantitative risk assessment purposes for many of our important pathogens. It may be that we can use the shigella dose response as a default, as defaults are used in quantitative risk assessment and make the assumption that very, very low doses can cause illness in a substantial proportion of exposed individuals until we have better data for various pathogens. I think the dose response curve for E. Coli 015787 is very likely to be similar to the dose response curve for shigella even though all of the pathogenic mechanisms aren't the same. What we know about 0157 suggests that they'll be somewhat similar. We certainly aren't going to intentionally expose various populations to 0157 so that we can get a better curve and I think that we're going to

have to recognize that our data won't be perfect in every case but we may not have to be perfect. As we've suggested in a number of other areas we don't need perfect information to make socially appropriate action. If we can at least divide food-born pathogens into those that are likely to cause disease at a low dose where time and temperature abuse may not be so terribly critical, where small numbers coming out of the plant may constitute some hazard in their own right, if we can identify those organisms and then identify those organisms that would require progressively worse handling before they would cause illness, I think that that may be good enough -- you know -- low, medium, high sort of qualitative characterizations.

MS. FOREMAN: Thank you.

MR. HODGES: Jim Hodges, American Meat Institute. I found the discussion this morning very interesting and there has been a significant amount of what I consider very thoughtful discussion put on the table. But I'd like to go back to some of the initial comments made by Glenn this morning. I highlighted it. The statement, and correct me if I'm wrong, the statement was that if the pathogen target, assuming that is salmonella at this point, the pathogen target is exceeded the conclusion is the HACCP plan is not working. Correct?

DR. MORRIS: This is one -- one conceptual structure.

MR. HODGES: I think that's a false assumption. Pathogens occur in a very random nature in the animal population and it may not be as a result of what happens in the plant. So to reach the conclusion, which comes back to Bob's legal premise, to reach the conclusion that there is something the plant can do or has not done improperly I think

is the wrong conclusion based on a statistical sampling program that says we have established certain incidence levels of pathogens. An example, to try to bring that to light is, if a slaughter, regardless of the species, brings in at the lot of animals that's being slaughtered is positive for salmonella, a hospital type operating environment will not assure that salmonella is not included on that product. If you sample that particular product from that particular plant you will have a positive incidence and by the statistics you could, over the course of time, reach the conclusion that this plant is out of control when it is operating in what I will, to some degree, call a hospital operating environment. You take the opposite side in that a lot of animals comes into the slaughter facility that is negative of salmonella. When that lot comes in and it is negative and let's assume that that plant has less than a desirable slaughter and processing procedure or HACCP program the sample you draw comes up negative which is the better operation? Is it the one that has the negative sample or is it the operation that had the positive sample yet was probably had better process controls? That's the fundamental reason that we think that indicator organisms are a far better indicator of the potential to achieve improved food safety. Indicator organisms in the form of E. Coli does -- are their numbers, they are measurable, and they can provide us the best opportunity for food safety improvement. I'm not arguing the fact that baseline numbers for pathogens should not be conducted. I think they should. But to judge a plant on those baseline numbers I think is very, very problematic.

MR. TAYLOR: Let me just ask a question, Jim. I understand

exactly what you're saying and let's hypothesize. I want to ask you a question. Let's hypothesize a plant that -- you know -- whether it's beef slaughter, broiler plant -- let's hypothesize a plant within the four walls of that plant has got a first rate operation. They're doing everything -- you know -- that you can imagine within the four walls of that plant in terms of the way in which they carry out their operation. But they produce, whether consistently or episodically, let's say consistently, product that exceeds the national baseline incidence of the pathogen that -- you know -- might be the subject of a target we would set. What is the appropriate public policy response in your mind to dealing with that phenomenon? Again, a phenomenon which out of that plant -- you know -- went through the chain of commerce is product that is consistently exceeding what the national average consistently is.

MR. HODGES: Well, first of all, if you're operating with process control I cannot envision that kind of scenario occurring.

MR. TAYLOR: Then we don't have a problem.

MR. HODGES: But it comes down to your sampling plan. If you take enough samples and you have a statistical confidence -- you know -- that -- that a plant is operating at above a baseline level then obviously there's going to be some kind of problem there. I mean if we go back to 015787 it's extremely low incidence rate at .1 percent. It takes -- it takes enormous impractical numbers of samples to get any kind of statistical confidence of what the actual level is in the population of the meat coming out of that plant.

MR. TAYLOR: So -- so --

MR. POCIUS: This plays into what I had started this morning

before we all got sidetracked. We're looking at baseline numbers and averages and we're saying that's the performance standard. Yesterday, when we talked about cooked product we talked about performance standard as benchmarking a 70 process -- reduction process or the cooling directive or whatever. In this case, what I suggest what you're after is a measurement of improvement, a measurement of pathogen reduction and we're not talking about that yet. We're talking about meeting a number. You don't know whether anybody's improved or not. Let me finish because if we -- some people -- other people have mentioned trend analysis -- what I have mentioned earlier today. If you look at this in terms of trending throughout the year you know during each time period where your true baseline is. If you then set a performance standard as a percent reduction against a known baseline at any time of the year you then obviate the arguments of at some time we will spike and you'll have higher numbers, even though it's a controlled plant, because you will not be measuring against a false baseline. I mean basically that's if you're looking at a twelve month national average you're not capturing all the variability.

MR. TAYLOR: Let me just ask a question and at some point Tom will send us away to have lunch but after we can talk about this because in the preamble to the February proposal we laid out as an alternative intro strategy for pathogen reduction, an alternative to using the national baseline and requiring reduction below that, the idea of establishing what would amount as an interim measure plant specific baselines and requiring some percentage reduction by each individual plant in relation to its current baseline. And I certainly --

which would mean that -- you know -- there would be some requirement that the plant establish the baseline through testing and then get a percent reduction. We expressed concern about that as a long term strategy because it needs to be a standard of performance that is national in nature and -- but I'd be interested in your reaction to that as an interim strategy.

MR. POCIUS: A national baseline average is good information to know if you trend it year after year and then you can say, well, the industry's improving or the industry's not improving. But you cannot hold individual operators against a single one year national baseline average because it does not reflect the variability at any one point in time that the operator is operating against.

MR. TAYLOR: If we don't -- again, this gets to the heart of how we achieve our objective. If we don't have a measure of accountability for each plant to use how do we --

MR. POCIUS: I'm not suggesting that you don't. In fact, I suggested that your performance standard be something different than the national baseline number. What I'm suggesting is that you want to measure change and improvement and your performance standard should be a measure of change and improvement, not the baseline.

MR. BILLY: Bruce?

MR. TOMPKIN: Bruce Tompkin. I'm Bruce Tompkin from Armour Swift Eckrich. Certainly if a plant was operating under a HACCP plan and was meeting its process goals and the agency were to come in and find that, in fact, that plant was producing a higher level of salmonella than the rest of the industry or at least the average that's

an opportunity. That's an opportunity to learn why. That's an opportunity to help others find out how to make improvements. I would suggest that in those circumstances that certainly you're going to collect more samples and the processor's going to collect more samples and hopefully as a result of that we will benefit from it and to -- of course, it's a regulatory concern and I can understand that. In the short term, shut the plant down is perhaps a -- one direction that you could go but I would prefer that we take advantage of that because we are looking for answers.

MR. BILLY: Angie.

MS. SIEMENS: Angie Siemens from Oscar Meyer. My question alluded to where Mr. Taylor went relative to the difference between this program after HACCP is implemented and until HACCP is in place. I know a lot of the conversations I agree with were well ahead -- once process control is in place, we have HACCP in place, that the validation of that HACCP plan and the verification of the program we still have some discussion on that part of it.

I do have some questions though of going back to an earlier question on developing some of the baseline data that you're talking about and establishing maybe a number in the interim. Are we going to be held to -- what is current thoughts on compliance relative to until we get into HACCP and the sending of information to you via the proposed rule in that you would be required to send the data to USDA in the interim such that you could substantiate a baseline at that point? So I know we've got two concepts going. I'm not sure we're talking some of the interim and where we're headed in that versus after HACCP and there's a distinguishing mark there, I think, between

those two programs.

MR. TAYLOR: If we were to shift from what we proposed in February to something like what we've put in the paper then it would very much raise that issue of whether the testing that we would require a plant to do for E. Coli as a fecal indicator whether those data would be useful to have submitted to us. They would not have the same utility obviously as a flow of salmonella data would in terms of building -- you know -- a baseline and so forth. There is a need to revisit that. I mean it's not clear what the utility would be of submitting E. Coli -- you know -- data. That's a very good question we would need to resolve.

MS. SIEMENS: What about salmonella testing until HACCP goes into place? If you're coming, and I don't know how soon it will be up and running with pooling your testing program prior to having HACCP implemented in the facilities, is there -- we're talking compliance once HACCP's in place and the validation of HACCP plans, etc., but what are your plans on going with that data that you collect until our process controls are in place and the terms of HACCP?

MR. TAYLOR: Again, these are all questions that we're in the midst of revisiting in light of possible alternative approach. Because we had laid out a timetable under the proposal where the companies would be doing the salmonella testing whereby you'd start the testing at a certain point, start recording and submitting the data to us at a certain point, and later on we'd start holding you accountable for compliance for meeting the target. That would all -- has to be revisited if we go this other route where we're doing the testing and we don't -- those are issues we invite suggestions on. Thank you.

MR. BILLY: I'm going to wrap this up. It's one o'clock. Let's take an hour for lunch and come back at two o'clock.

(A luncheon recess was taken)

AFTERNOON SESSION

MR. BILLY: Would everyone be seated please. Several people mentioned or raised questions about both sort of agency and plant accountability and enforcement in the sense of what happens if with regard to use of E. Coli or salmonella or other things. If you'll notice that on the agenda for yesterday under Item C there's a whole section on insuring compliance with HACCP requirements. There are several billeted items under that. I think it's another item like timing that probably fits best in terms of sequence towards the end of these meetings and so my suggestion is that we move that entire section to the last day -- the 29th -- and it would enable us once we complete this discussion do further thinking in the intervening time with regard to furthering this approach that was put on the table this morning and how it would work in terms of both accountability and enforcement. So that's my suggestion and my intent unless there is some major objection. That would mean that on the 29th, in addition to the items we've identified, we would have the discussions on timing that are -- that were earlier on the agenda as well as the discussions regarding insuring compliance with HACCP requirements.

When we left off we were talking about the billet items about salmonella as the appropriate organism. I'm quite sure that we didn't finish that. Whether other pathogens would be preferable and then the utility of targets for E. Coli and other non-pathogenic indicator organisms as means of controlling or reducing pathogenic organisms. I think it would be useful -- there are several people that we haven't called on yet -- haven't spoken yet today and complete that and the next two items as well and then during the lunch break we were

talking and thought that perhaps in the context of measuring achievement, where we're talking about the purpose of testing, frequency of testing, maybe it would be worthwhile to talk about that area under sort of this new thinking, both with respect to near term and then under HACCP and discussion about how we would use E. Coli and separately some pathogen performance standards for both near term and HACCP-based approach. So I want you to be thinking about that because we'll get to that a little later this afternoon.

So right now I'd like to finish this discussion. There are several people I haven't called on yet. Eric is next on my list.

MR. JUZENAS: Eric Juzenas, American Public Health Association. I've been happy to hear from the Administration that acknowledge that this really is a public health issue primarily. It's also an industry issue because that is where the changes need to be made but it is primarily being done to protect the public health. One of the reasons that is necessary is that the public doesn't have confidence in the system and any of the changes that are made I think you need to take that into account and need to make sure that the public is going to have confidence. Due to the inadequate scientific background that's been noted by both people here, the National -- the government -- let's see -- the GAO and others and the fact that HACCP as a plan for the entire country hasn't been fully tested, I think that any errors that we're going to make to be made in the direction of public health. For that reason we need to consider about what types of things inspire confidence and might protect the public health. I don't think testing with E. Coli alone which provides indirect data about specific diseases would necessarily accomplish that. I don't think that

allowing lines to run for weeks or months while moving point sum catches up to a level where action is deemed necessary the HACCP needs to be looked at necessarily accomplishes that. I certainly don't think that saying we don't know about seasonal spikes that occur and contamination accomplishes that. I think with things like that there's clear public health things that can be done to address the problem and make it better. Lines can be slowed down. Trucks can be less crowded. It's not a matter of we don't know.

As far as microbial testing, I think during the interim that it should be considered of doing parallel testing of E. Coli and salmonella. E. Coli, as has already been noted, provides a great measure of fecal contamination. Salmonella will help provide a paradigm where we can start looking at how we can test for specific disease-causing agents that are directly affecting the public health. This will help in developing models of contamination providing a broad picture of what's going on in the nation as a whole and also bring the basis to move to health-based standards and away from national baselines. I think those are all valid interim measures but since the long term goal must be to protect the public health I think eventually the only standards we can do are health-based standards.

The other issue which you mentioned and I think is coming up this afternoon is testing frequency and I would love to hear some discussion about how exactly the moving point sums when it's my understanding that a beef plant could operate for up to two months without actually achieving the moving point sum going above the HACCP violation whether that poses a health concern. It certainly raises a matter of public confidence and two months seems like a

long period of time. For that reason, it may be practical to require perhaps for small manufacturers a minimum of one test per day but for larger manufacturers either two tests, three tests, or based on volume. I think since the largest place having the more frequent test periods will, if we continue with the moving sum average, allow that average to catch up more quickly when there's a problem. The goal here is really primary prevention and many people have noted the fact that we're not going to obtain zero risk and, in fact, in no public health situations are you going to attain zero risk. That's a red herring. But we can definitely target our procedures and our processes to do better than we're doing today. Thank you.

MR. BILLY: Caroline?

MS. DEWAAL: Caroline Smith Dewaal with the Center for Science in the Public Interest. I want to build on what Eric said in terms of the issue of confidence. And what we're really seeking speaking on behalf of CSPI and a lot of groups who participated in our comments is confidence in USDA's new program. I am concerned today to hear of a move away from pathogen specific testing and I think it's good to, at some point today, look at the difference between the interim testing requirement and where you are going with testing in HACCP generally. But I'd like to pick up on something Jim Marsden pointed out and that is that we have identified in our comments at least two roles for micro testing in HACCP. The first is validation and identification of critical control points. And the second is for verification purposes as a feedback system for HACCP. I would urge the Department to consider separating those two goals. I think that for validation purposes pathogen specific testing is appropriate. We

are -- HACCP is designed around identification of hazards associated with your product and then developing process controls to control those hazards. Unless you're testing to make sure your plan actually accomplishes that objective then I don't consider your plan validated and I think that in developing the final rule I think you really need to look at what is the role of microbial testing in HACCP plan validation. I think what we're discussing today is the verification role of microbial sampling. I'll remind the Department we did recommend the use of E. Coli -- generic E. Coli -- in addition to salmonella. And we do agree that industry should do the testing for verification purposes. I think, however, the Department needs to define the times at which not only generic E. Coli testing is performed for verification purposes but pathogen specific testing is performed for validation purposes. For example, if a plant has new equipment coming on line that would clearly be a time at which validation -- revalidation of the HACCP plan should occur. Changes in incoming product which we've talked about today. Again that might be a very good time for revalidation and rechecking the system using pathogen specific microbial testing. Also, new employees are always going to be an issue and maybe that can be taken care of with verification sampling but I think there should be some regular revalidation of HACCP plans using pathogen specific microbial sampling. Whatever control is chosen, the Department needs to be very sensitive that it's going to drive the development of the HACCP plans. I raised this in our comments with the idea that -- you know -- if you control for salmonella it's somewhat easier to kill using an anti-microbial rinse. You might get very good results on salmonella and still have major pathogen

problems with your product so I -- I -- we don't -- no one has all the answers but I really would urge caution in picking these -- these indicators and to look at what the unintended consequences of choice might be.

And, secondly, you really need to look in this particular proposal of separating out and letting the Department do pathogen specific testing or pathogen testing at all and having the industry do generic E. Coli testing. Are you allowing the industry to avoid its responsibility to control those specific pathogens? I would -- I would urge that is the industry's duty to do that and that it should be mandated at some level as part of the final rule.

MR. BILLY: Jim Marsden.

MR. MARSDEN: Thank you. I actually raised my hand to respond when Under Secretary Taylor asked for some specifics about the science of process control and how this concept of performance standards applies to using the science of process control.

What it appears to me the agency's attempting to do is use statistical process control principles to demonstrate whether or not an establishment is operating under control relative to the output of their product and attempting to use salmonella as an indicator of that. And that kind of system, scientifically, can work but it frankly cannot work the way it's been proposed. In order for that type of a system to work, you would have to develop a mean based on each establishment, probably each line within each establishment, based on historical data and establish the variance around that mean and you then set up upper and lower control limits around that mean based on the standard deviation which, again, is based on the variance and

statistically ninety nine percent of the time that plant, if it is under control, the numbers will be within three standard deviations of that mean plus or minus. That's just a statistical fact. About one half of one percent of the time the number will be over three standard deviations even if the process is under control and when that happens repeatedly some plants use two times, some plants use three times, three numbers outside that three statistical process or standard deviation limit, that's an indication that the process is out of control and action is required. So long as the plant is operating within those three standard deviations of the mean scientifically that establishment or that line would be under control. Now that works in industry. It's used in the automobile industry, pharmaceuticals and so on it works very well as a model. But when you start looking at an industry average it changes everything because an industry average is not the same thing as the average that's established from historical data on that line. It's probably got much more variations associated with it. It doesn't necessary reflect the capabilities of that particular line and that particular establishment and as a statistical model, as a result it doesn't work. So in order for this model to use statistical process control as a model to work, it's going -- it would have to be done on an establishment by establishment basis. It statistically doesn't work otherwise and there's books written on this subject and all kinds of things and it starts to get some of the things that Jim Hodges and Joe Pocius were raising awhile ago. I mean those are legitimate concerns. If you establish the historical data in your plant then it takes into account some of those things. It's not that you operate out of control as a result or that it's any kind

of excuse, but it becomes a manageable process.

MR. TAYLOR: Jim, this gets to a very critical point as to what our objective is and I just need to play back what I'm hearing you say and correct me if I've misunderstood. But your emphasis on historical data and experience in that plant as the basis for determining whether the process is currently in control or not at least implies that you're suggesting that plants be responsible for -- again, I don't mean to over simplify what you've said -- but what I'm hearing is that, as you've describe it, plants be responsible for continuing to do consistently that which they've done historically. That -- that's not what this about. This is about having some understanding based on what others in industry have demonstrated as achievable with current technology. The philosophy is to bring about change where necessary to meet what would be judged an acceptable level of performance.

MR. MARSDEN: You're totally correct.

MR. TAYLOR: Plus this control of drug manufacturing, for example, is certainly not based on historical experience. It's based on achieving a stated end product specification and having a process that's built on all these statistical control procedures you're described to achieve an end product level of performance -- standard of performance specification. And so I'm missing some -- I mean there's a disconnect between us on what the objective is.

MR. MARSDEN: Right. There's more to it than that and what's -- the part that's more to it is if a process fails to meet a performance standard, if the capability of the process is such that a plant is operating consistently below that performance standard -- it's not meeting that performance standard -- that means the capability of

the process for whatever reason is not -- is not sufficient to produce, in this case, safe product, which means that you have to improve the capability of the process. Maybe you're talking about new equipment or better sanitation or looking at raw materials. Any number of factors -- you know -- could be responsible for that but in order for it to work and that model to work you can have -- you can have a national performance standard -- okay -- you could set a standard like you have for E. Coli 015787 in ground beef, for example, and then plants can determine whether or not their current operations meet that standard given the variability around -- you know -- that occurs naturally around that line or, if not, what they have to do in order to meet it and that will work. That kind of a model would work at least scientifically. I don't know whether it would work from a practical point of view. There's all kinds of small business considerations and cost considerations that play into that. But if you're going to use statistical process control as a model that type of model would work versus just as a company above or below an arbitrary national mean they could be above or below that mean on any given day and that number wouldn't really truly reflect what's going on in that establishment. There's just natural variation that's going to occur and it's just going to be almost random chance.

MR. TAYLOR: And that's what the moving sum statistical procedure was intended to account for but --

MR. MARSDEN: And it does, at least in part, begin to account for that and you wouldn't take action until -- you know -- the plan exceeded that certain level and I recognize that, but nevertheless, when you use that national average as your base point you have to

recognize that almost by definition takes you out of a classical statistical process model by definition. And that's the weakness in that approach.

Another thing that -- we're talking the science of Dooming here who used to work at USDA by the way at one time in his life. The other part of this that we had mentioned is the concept of continual improvement -- that that's implied in this whole process -- that you do better and better and better and hopefully with each day and your performance standard really becomes zero. You may not ever achieve zero in terms of defects or whatever but that's implied in that process that you're not just taking the status quo and living with that forever but you're trying to always move forward to do a better job of improving the capability of the process.

MR. BILLY: Dane?

MR. BERNARD: Thank you, Mr. Billy. Dane Bernard, National Food Processors Association. The term validation keeps coming up and we've heard again that testing specific pathogens must be part of validation. As I said this morning, that may be a part of validation but we have to look at the individual process and product. We were talking about cooked products yesterday and the performance standard for that being a 70 kill, let's say, for poultry cook. And I understand the plan to at least test three commercial lots once the process is set up as a validation procedure. In that case to test finished product for presence of salmonella as proof that we have accomplished a 70 kill simply doesn't make scientific sense because the initial contamination load is going to be nowhere near that level and if the bugs aren't there in the first place then it makes no sense

to test for the them in finished product so in that particular instance and many others it would make very little sense because the information that you would get scientifically would not validate the process so you need the flexibility to be able to utilize the best scientific techniques available to validate the process and that is not always testing for specific pathogens on finished product. In certain cases that may be so but not universally so I would hope that the agency would consider that there may be better methods of validating processes when we get to that point. Thank you.

MR. TAYLOR: Dane, I just want to make sure you're clear that the proposal we're discussing today is -- applies solely to raw product. We have not proposed any salmonella or other specific testing for processed -- for finished processed product. In the context of validating performance standard alternative for cooked products we talked about yesterday, testing would be part of validation but we've not -- this interim target for pathogen reduction concept is with respect to raw product.

MR. BERNARD: Thank you for that clarification but through the discussions today that hasn't always been clear because several from the floor have mixed their whole concept as to where we're going and I might -- you know -- add as a tag line that even when we're dealing with raw products one must consider the prevalence of the organism that we're targeting in terms of whether testing for a specific pathogen is indeed going to give us results that will give us faith in the validation of that process. We certainly don't rule it out but just to say that we tested for something and didn't find it just means that we've -- specifically that -- that we didn't find it, not that the

process that we submitted that product to was indeed a valid process. Thank you.

MR. BILLY: Mike?

MR. ROBACH: Mike Robach, Continental Grain Company also here with the National Broiler Council and in the view of speaking about raw product, getting back to looking at E. Coli, I would like to refresh everyone's memory on the results of the second scientific and technical conference which was held in Philadelphia which was the role of microbiological testing in verifying food safety and in the expert panel summary report and recommendations I think there are some very germane points that need to be addressed and inserted into the record once again. Really, microbial testing, in the panel's view, was a function to demonstrate process control and there is a very strong need to base process control with respect to fecal contamination on approximate indicator for enteric pathogens. Microbial testing for process control must not be confused with lot acceptance testing. And with that purpose in mind, the panel concluded that E. Coli would be the most effective measure for process control for enteric pathogens. The panel did an excellent job, I think, in assessing the information presented to it at that panel and they looked at the various characteristics that needed to be considered. Some of the more important ones are association with the presence of enteric pathogens and in the case of slaughtering the presence of fecal contamination. Higher frequency than salmonella and quantitative nature of analysis permits more rapid and more frequent adjustment of process control. It should also have similar survival and growth characteristics as the enteric pathogens. It also

addresses laboratory safety and a greater feasibility for in-plant analysis as Dr. Brown mentioned this morning and it has to have a wide acceptance in the international community as an indicator of enteric pathogens. And I think, clearly, E. Coli meets those criteria as an indicator of both process control and also as an indicator of the potential absence of enteric pathogens.

One of the other issues then taking on that is looking at targets and how that can fit in to a program of process control. And the first thing we have to understand is that available literature and published data do not provide the information we need for a baseline. Sure, companies have been doing analysis for a long, long time. However, that analysis has been done by different methods, different sampling techniques, and to go back and try and combine that into a data base that would be meaningful it would be impossible and wouldn't be scientifically valid.

So the panel has looked at this information and suggested that the measure of process control could be considered thusly. First, that the level of E. Coli on chilled carcasses shall not exceed the level present on freshly defeathered, dehaired, or dehided carcasses. It takes into consideration the animal that's arrived at the plant and is a more accurate view of process control that you are not increasing numbers through the process but you are reducing numbers through the process. Seemingly, your process would be in control if that's what your result was. The second issue relates to continuous improvement. This information could be generated in a consistent manner which then could be the basis for a baseline which then could be used to measure continuous improvement against taking into

account -- it would have to take into account in the development of this the seasonal variation and day to day variation we see as we process a biological animal. Unfortunately, unlike pharmaceuticals and chemical processes, cows and pigs and chickens don't always enter the plant in an identical fashion and we have to take into consideration this biological variation as we're establishing a program that gives us the confidence we need that we are doing a better job in the area of food safety.

MR. BILLY: Caroline, did you want to say something about what --

MS. DEWAAL: Yeah. We heard a number of times today that the -- the companies can't control the condition of the incoming product and I want to remind you of a couple of episodes where the lack of that control, even in the presence of HACCP in plants, resulted in major outbreaks -- Schwan's Ice Cream -- they had HACCP in their plants, they had control product that came to them contaminated and they sold a ton of ice cream in a bunch of states and caused something like five thousand illnesses from salmonella. San Francisco Salami Company, I believe is the name of the company, they also -- incoming product contaminated with 015787. The bottom line is, no, you can't always control the condition of incoming product but it should be a critical control point. It should be one of the things you look for. If you -- if there's something utterly surprising and you don't find it and it slips through then maybe then it will come out as part of your end product testing. Maybe it will come out as a weird result somewhere else along the line. But you should be able to control incoming product. I mean this is something you purchase or

something you control that's going into a product potentially with your name on it. It's something that if you are just giving up a lot of responsibility to say hey, I can't control the product coming in to me so I can't control what goes out my door because you're the only one who can. That is -- that is a control you have along the chain -- the farm to table chain -- to -- to making the product safer so I guess I just have to object to this concept that industry can't control incoming product.

MR. ROBACH: This is Mike Robach back again. I don't want to confuse two issues that I think you've confused. The incidents you mentioned are ready to eat products. What I'm talking about is a raw ready to cook product and I think there's a big distinction between the two products. When I'm preparing a product that's ready to eat it is just that -- ready to eat. When it's ready to cook it is that -- it's ready to cook and it may have pathogens on it because my process is not capable of eliminating those pathogens so I think there's a distinction you need to draw between ready to eat and ready to cook products.

MS. DEWAAL: I think -- I think that you still can exercise control at the door of the plant on the product you bring in and I think if you don't or if companies don't they're not fulfilling their responsibilities in the farm to table continuum.

MR. BILLY: Okay. Joe?

MR. MAAS: Hello. My name is Joe Maas. I'm with JTM Provisions. I say that and probably nobody knows who that is but I'm used to everybody else saying -- --. I know just who they are.

I'm trying to still be as careful as I can so that I don't feel like

I'm representing all small business although I have association with a lot of small businesses my size just through -- from a social standpoint.

Once again, there's been some talk in the last couple of days with regards to large and small companies meeting the same requirements but I think that it's important to point out that small businesses tend to be much more motivated to insure the safety of their products when they leave the plant -- that they have a higher degree of economic motivation in a small plant possibly than in a large plant.

My question is, is if that's true, in my plant I have -- if my micro population is -- exceeds your expectation, exceeds the baseline currently, today, whatever the baseline is -- you know -- my micros in my plant are -- are -- exceed -- I don't want you guys to keep saying above and I don't know if that means below or above -- but if they exceed or they're better than what the baseline is I wonder -- I wonder why it's important then in my plant or in any small business's plant that they would have to be mandated to institute HACCP. I believe that on a -- that small plants experience the economic burden of putting these plans in place, maybe to a larger degree than large plants, and I believe that they're currently motivated to put out a safe product to a greater degree than maybe what large plants are. So maybe that's one reason why small plants might get a different consideration than larger plants.

And the second thing that I wanted to point out that without making this too long that we keep talking about trying to reduce the incidence of occurrence of illness in the marketplace and back in --

in the history of my life I was in pharmacy college and there was a theory that was always brought up in class that there is what is called the hundred percent theory -- that if a patient experienced a specific drug effect -- a side effect of a drug -- then it's a hundred percent with regards to that patient. My point is that I'm not sure that just lowering the incidence of occurrences is really going to be that beneficial. If my kid gets ill I don't care if you've lowered it from ten percent to nine percent it's a hundred percent as far as I'm concerned. I don't know that you've done anything. I just wonder exactly what the -- I just have a hard time understanding -- you know -- where this whole thing goes. I think that overall hopefully we can -- you know -- maybe do more in education long term and maybe that might have a better impact in resolving a lot of these issues.

MR. TAYLOR: Joe, let me just respond particularly to your first question but I'll also say something about your second.

The conceptual answer that -- to your question about if you're meeting some pathogen target or other microbiological target why should you have to do HACCP and the conceptual answer to that was out in the conversation very prominently this morning and it is because from a conceptual standpoint the belief is that -- you know -- producing a safe product doesn't happen by accident and we need -- and so you need some form of process control coupled with some measure of accountability for achieving it. In your plant, and as you've cited the last couple of days, you obviously invested more energy and effort, you've got a plan for producing safe product and I can understand the question than well, why should you have to conform to this HACCP regime? I guess our challenge, I think, as an

agency, in light of the -- of what we've heard from commentors across the board about the desirability to have a basically a national -- you know -- consistently applied HACCP program -- our challenge, I think, really for companies like your's that are up operating -- you know -- aggressive quality -- you know -- safety plans, if you will, is to make your compliance with this new regulatory requirement absolutely as easy as possible. If you're already doing all the things that need to be done in terms of hazard analysis and you described it -- you know -- very practical terms yourself, we're not wanting a regulatory requirement that -- that requires effort that is not productive towards producing safe product and -- you know -- that is form sake so, on the other hand, I don't think you asked for an exemption from the HACCP requirements so the issue is how can we, through whatever means in terms of whether we write the regs and the assistance we provide, make it as easy as possible for you to be -- to comply with the requirement.

MR. MAAS: I would say that's fairly accurate, Mike. Overall, in keeping in mind the economic burden that might be placed -- you know -- it's a function of -- I mean I spend money every day to make things better. I am -- I spend money -- it's incredible what it costs to just do anything every day just to make things better -- but, you know, I just don't spend any money if it doesn't make it better. I don't spend any money -- I do not have that kind of powder so to speak to -- to spend money on things that sugar coat things. I only have the money to spend to make things better.

MR. TAYLOR: Right. Well, your second point, I agree with you, that from an individual human standpoint, if you're the person who

becomes ill or suffers a loss of family member at a personal level it doesn't matter at all probably or at least not a great deal that we've reduced the risk of food-born illness in the country. But if we do -- you know -- reduce significantly the incidents of contamination of raw product with pathogens in the first place we have reduced -- we believe that will lead to reduction in the number of people -- families -- who are at risk from that risk being rendered unsafe through the growth of that pathogen and subsequent -- you know -- consumption of a product that's unsafe. So, I mean, I recognize that we're dealing here with sort of broad public health and so forth and we're not going to eliminate illness.

MR. MAAS: I'll acknowledge that as well, Mike, but I'm not -- I am yet to be convinced and it's yet to be seen and I asked Tom at the Crystal City meeting -- you know -- we're going -- I guess we're going to monitor this baseline, we're going to look at public -- at incidents of public illness and we're going to monitor that over the next three to five years and my question was, is after three to five years if the baseline doesn't move, if public health is not improved, if food-born illness occurs at essentially the same rate, then are we going to -- are we going to then maybe remove this HACCP regulation from the books because it carried no effect and it only placed an expense and did not have an effect -- a positive effect? That's the question.

MR. BILLY: Beth.

MS. LAUTNER: Thank you. I thought I might have this baby before I got a chance to talk. I have made comments about trusting veterinarians more than M.D.'s a little bit.

When I wanted to speak was when we were talking about baselines exceeded as far as pathogen testing and what action would be taken and one suggestion was not allowing the plant to operate. I guess what concerned me was talking about imposing regulatory standards with compliance monitoring when have some critical lax of data in really two areas. We've talked about salmonella being out of the packer control and looked at the producers and I am with the National Pork Producer's Council. And I think it's also a valid point that the salmonella types of programs are really not developed to the situation where the producers really have those in their control as well, both when you talk about salmonella in herds. It's random between herds and then within a herd -- very randomly distributed. There's a lot of research that's being done -- both USDA and the industry -- to look at this research epidemiology transmission, detection techniques, management intervention strategies, the impact of transportation, the impact of feed withdrawal. We're involved with Iowa State in bringing a researcher over from Denmark that's worked with their system there to look at how it would apply to this country. So there's a lot of work being done in this area, a lot of work starting to fall through in interventions on the farm and follow through into the plant to see if that can carry through. But at the time, we don't have the data for the packer to come to the producer and say, do something, fix this before this animal reaches my plant. That's my first concern about the lack of data.

The second concern is about actually setting the salmonella standard with regard to pork and in the Federal Register notice there is some discussion of this of the fact that there's been few studies of

salmonella in pork carcasses and comes to the conclusion in the regulation that they used Canadian data for what the U.S. baseline should be if we have to take a number now. I've been on over thirty farms in Canada. They do have some different situations and different salmonellas so I think there is some question about how valid that would be to take a Canadian sample. And, in fact, in the next paragraph it talks about Canadian samples of turkeys and notes that their level on turkeys was four times what the U.S. standard was and said, well, we won't use the Canadian numbers, we'll use the U.S. numbers and then the next paragraph says we have no data for baselines of other species so we won't look at other species.

My point with all this is that as we look at trying to put together a bunch of disjointed data that's been collected from different isolation techniques, some collected before chilling, some collected after chilling, some at side samples, some swab samples, sponge samples, at different seasons, different isolation techniques, different sensitivities, and when you take that information and then ask industry to give you some more information and kind of mix it all together and then come out with a number that's not necessarily good science and it can be that poor that as not as good as no data. So I guess my point with it is that if you're going to look at doing some type of compliance monitoring with a number that we have to have quite a bit of confidence in the validity of that number.

MR. TAYLOR: Beth, what's your suggestion for how we do that -- gain that confidence?

MS. LAUTNER: I thought you wouldn't let me make a comment like that without saying. But I think in our comments what we

suggested was that it be more appropriate to have the baseline data put together for pork because as you look at these studies and I did some of this review of looking at these studies people were using all sorts of different techniques for isolation and swabbing and those types of things and the seasons have an impact and those types so I think it's important to look towards FSIS's baseline data.

MR. BILLY: Lee?

MR. JAN: Lee Jan with the National Association of State Meat and Food Inspection Directors. I just wanted to get a clarification of the first comments from this morning Dr. Morris made about the E. Coli testing and then the salmonella testing by the FSIS and what I understood may not have been exactly what was said or it's not the same as was understood by others because from what I was hearing later in the morning was about taking grant away or taking some regulatory action against a plant that didn't meet the levels or they didn't meet the standards. It's my understanding that E. Coli would be under this current thinking that E. Coli would be the organism to use to test process control and that FSIS would sample for salmonella much like today's national monitoring program that would be done on a random to see that the industry standard has decreased or industry average has decreased. That's what we have our knowns for now. But then, like I say, later on in the morning I've heard some comments and questions about what happens when a plant exceeds those standards or those averages or we're going to close the plant down so that brings to mind is if the intent is that the plant do the testing for E. Coli to verify process control and then FSIS does testing to -- for salmonella to prove that the plant -- that each plant is meeting

average goals then that's going -- it seems to me that's going to be a lot of testing that's going to be done by FSIS and I'm not opposed to any testing that FSIS wants to do as long as they pay for it but then when it comes to state programs or -- and we are equal to -- are we going to be able to send samples to FSIS laboratories because we're not getting money with the mandate. So I guess I got two questions.

MR. TAYLOR: You've all but spoken the magic words of unfunded mandate and that's something we have to -- that's a very important question -- consequence of the states are taking an approach like that and -- you know -- that's something that needs focused attention. I mean I don't have obviously an answer right at the moment.

You raised an issue though that we were talking about a good bit over lunch and in terms of clarifying sort of what our current thinking is I'd like to play back what you said and then pose a question to you and to others because we did speak this morning about the possible regulatory consequence of a plant under this model we put on the table yesterday, the possible regulatory consequence of a plant being found not to meet the pathogen reduction targets say for salmonella, if that's the organism. We talked about how that would put the agency in a compliance mode and we'd go back and say you're not meeting the target, you need to correct your process, and at some point if a plant was unable or unwilling to meet the target then that could result in this sort of regulatory action that you mentioned in terms of including withdrawing inspection. And that's sort of our current thinking about the consequence of not meeting that pathogen reduction target. It is a separate question. If we, under this construct, adopt generic E. Coli as a process control indicator what is

the appropriate consequence and this is the plant would be -- under this construct the plant would be conducting some form of testing to determine whether that performance standard for process control was being met, what should be the consequence of the plant finding that that performance standard is not being met and that's something on which our current thinking is not as developed as our current thinking on the issue of the consequence of not meeting a pathogen reduction target and I would ask for your view and the view of all the process control experts and food safety experts in the room what the consequence should be.

MR. JAN: Well, my view would be if you're talking about the plant testing -- part of the testing the plant does and it doesn't meet the performance standard which has yet, I think, to be established but whatever that happens to be if they don't meet it then it's their responsibility to look at their processes just like they would if they were under a true HACCP and look at their process and if they fail to meet it then it would be -- I have no problems going through with what the proposed rule was. I mean if you fail to meet it and even after -- I mean you have other options. You can change -- you look at your process, you change -- make the changes. Maybe it's time to add microbial wash or prewash or whatever, but after you've made those changes and you still are unable to meet within that period of time then I think you do have to go through that process of suspending or withdrawing the product or going to a fully cooked. I mean -- you know -- like you would another process. It goes to cooking like for TB or something.

MR. TAYLOR: Would it be possible, Mr. Moderator, if we just sort

of invited -- you know -- any other comment on the specific point of if we were to adopt generic E. Coli as a process control performance standard, if you will, an indicator of process control and subject to testing by the plant, what is the consequence of not meeting the standard. I mean I just would appreciate views.

MR. BILLY: Dane?

MR. BERNARD: Thank you, Mr. Chairman. I would agree with the tact that Lee has suggested here. I think everybody has to understand the dynamic of putting together a HACCP program. We were discussing yesterday and it has somewhat to do with the topic that we kind of wound up yesterday with pre-approval. You can get the best experts together and you're going to sit around tables and you're going to draw up something that looks good on paper and after some months you're going to take it to the plant on Monday morning and you're going to put this thing into implementation, you would, by noon, you're pulling your hair out trying to figure out why this thing doesn't work. It will happen and if you're using E. Coli as your performance standard or whatever it is you're using as your performance standard you're going to find that things are not working quite right. So you go back to the drawing board and say, okay, well, it's not working, our limit's not right, have we not identified the right critical control points. It's a dynamic process and everybody should understand that. This thing is going to be modified in the first few months even in a single process weekly. You're going to be making changes. It may be major changes or it may be just a nip and a tuck but until you -- you know -- it's a constant process. It's not just validation and revalidation. It's a constant process of looking and getting this thing

to where you're satisfied with it. And it's exactly what Lee was saying. If you're not meeting that performance criteria then you figure out why you're not meeting that performance criteria and you make those adjustments. But keep in mind -- you know -- the discussion we had yesterday, we're not going to do a HACCP plan, go put it in, and it's going to work. Forget about it. You're going to have to make those adjustments and you're going to have to be fluid with this thing and do what you got to do to make it work. Thank you.

MR. BILLY: Jim?

MR. LOCHNER: Jim Lochner. I'm going to make one comment at the end but I'll save it. The specific thing that you asked -- the specific subject matter -- what do you do is very difficult. Anybody's who tried to solve a microbiological problem in a plant recognizes that it is sometimes months and sometimes they go away and you have no idea why. It just got better. You don't have the luxury of changing one item and seeing a cause/effect relationship. Normally it's a situation where you go through all your critical control points, all your GMP's, all your sanitation, and if in doubt, change it and get focus on it. So any number of them -- one or many things -- could have caused the -- the improvement or conversely normally it's a series of minor adjustments that are needed to get it back into control. If you could waive a magic wand it would be easy but that isn't the process. The process is finding out and it's several things and I've tried numerous tests pinpointing specific areas for both looking for E. Coli species or spoilage organisms and quite often it goes back to basics but about one out of every eight to nine -- ten times it's something so bizarre you would have never thought of it

and it falls into the surprise curve so it's going to be difficult to mandate an enforcement activity on something that is very difficult to go after. But the only thing you can do is go back through your process and continue to make sure that you comply with your own critical limits but it may not be entirely obvious.

MR. BILLY: Carol? Caroline?

MS. DEWAAL: I just at some point when there's a -- when a plant continues to fail to meet its performance standard for E. Coli they need to revalidate that plan. I mean it may not be the first time around but at some point it's not enough just to go back through. You should need and you should mandate formal revalidation and if the plans don't work then -- you know -- then the validation will show us that.

MR. BILLY: Bruce?

MR. TOMPKIN: Bruce Tompkin from Armour Swift Eckrich. One thing that happens when you're not meeting a criterion and it may be your own or it may be a government in this case it's not been mentioned -- you start collecting a lot of samples and you analyze the data and it's the data that lead you through that maze of trying to determine what went wrong, what is wrong, what needs to be done to correct it. And in the fact whether that is a problem and the extent to which it may be depends on how tight that criterion is that we're all talking about. That's an important number.

With regard to process control systems and how we go about this it's not been mentioned but there are different ways of arriving at a number that a company may use. For example, today for a perishable raw meat or poultry product. One way of doing that is to

do what we call a flow sheet sample. That involves collecting samples of the product at various stages during processing, analyzing those samples, and determining which steps in the process cause an increase or decrease in a microbial population. That information is used to allow you to understand what's happening and where you can, in fact, exercise control. And that's how you can -- it's that information that allows you to pinpoint perhaps certain PCP's in a process. And then once they're identified you may not take any more samples at that point on a regular basis but only on an intermittent basis and particular if you have a problem. Now, eventually if all goes well, it's very common to get into the situation where you're only testing at the end of that process and in this case it could be at the end of chilling for a carcass product -- carcass. You have a number to go by. It would be your corporate number and in this case it could be one that's going to come out of this deliberation. That's your target. If you find that you're not in compliance or you have a trend showing you're going out of compliance then you have to go back and start flow sheeting again. It's -- because the fact that the microbial population is not visible, you have to rely on microbial tests. Those basically are the eyes in the system. That's really how it's done from a -- within industry and it works favorably in terms of meeting certain goals, whether they be for shelf life or for food safety goals and that sort of thing.

And as long as I do have a chance now to speak responding to your earlier question as to the relative merits of E. Coli I think it's a very practical target organism for process control. It's an effective means to learn what we need to know whether we are in control and

Barry Marshall's not here but it does have international consensus as an indicator of fecal contamination and Jack is indicating he would agree. So I think that it will fit in well with anything that should come about relative to Codex or anything -- international trade that we're going to deal with. Certainly the National Advisory Committee supports that concept in light of what they just -- their recommendations to you. So I think the direction of going toward E. Coli is a step in the right direction for industry to assess whether they are in control or not.

With regard to the agency, I think it is important to maintain some testing for pathogens. It's been needed all along. It's not a new requirement or desire. This should be -- we should have had this kind of data in place, program in place for twenty -- thirty years. Salmonella's not a new problem. It goes back a long way and it's important because we're going to through some fundamental changes in inspection, regulations. I know there's a lot of interest now from the farm to table. There's a lot of activity at the farm level as Beth has mentioned. We should be able to measure those changes. We need to know whether we're making progress or not and we want to know where we are relative to pathogen testing or the incidence and prevalence of pathogens and salmonella is an example of what you could test for but you may want to modify that by species of the animal.

So that's an important goal for this -- or target. We want to know where we are and where we are going. The other aspect of pathogen testing on the part of the agency is what do you do when you have a plant that seems to be or on the basis of your data has been

non-compliance with a target level or, as I'm going to call it, a performance criterion?

You do have a model for listeria monostogonese (phonetic sp.) in unpackaged bulk product. You do not take action on those products if you find a positive sample. In fact, what you do, the plant is notified and then you go back to re-sample. Now, and then that gives the plant an opportunity to generate samples. They can do their own testing, they can investigate, but they really need to get prepared in the event you do return and, in fact, they have to determine -- they have to do that testing anyway to get their own level of confidence up. So taking action on an individual set of samples goes against what we've been talking about with regard to HACCP. HACCP allows you to look at a lot of data and in the event a plant has a problem you do have the E. Coli trend data to look at. There are other data generated at various steps and CCP's that data's available. So you're not really working blind with a set of salmonella results. You really have an opportunity to go back and look at the other data. I think what that does, it gets away from the snapshot approach of inspection. It allows you to use all these data and to follow trends. Unfortunately, what's been mentioned so far by several individuals -- Jim Hodges started it perhaps -- but it is unfortunate that there -- live animals -- the presence of certain pathogens in live animals is intermittent and it's -- if you look at the data and literature that is a very significant factor influencing whether a plant has a salmonella, for example, in its product on a given day for raw meat or poultry. So on that basis alone it's important that you not take action on a single sample but go back and repeat and I think that through

microbiological testing we can get to the goal that we're seeking. Thanks.

MR. BILLY: Bruce?

DR. MORRIS: Let me just pick up on something you said about halfway through there. I mean one -- again, one of the open issues here is what the appropriate pathogen is for the targets and you had indicated that salmonella appeared to be reasonable, although not necessarily for beef. I mean would you care to indicate other possible pathogens which could be used for establishment of target -- very specific product groups or commodity groups?

MR. TOMPKIN: Of course, in poultry group it's salmonella or it's campilobacter (phonetic sp.). That would seem to be -- either of those would be more appropriate for a pathogen but in a laboratory you're going to want -- I prefer testing for salmonella. It's a hell of a lot easier. Beef is a lot more difficult because of the lower incidence and so finding an alternative for salmonella with high prevalence, fortunately, I don't know that we have such a pathogen and that's a good position to be in. The fact that we don't have a high prevalence of something else is good. So it makes your task more difficult in assessing whether a given plant is, in fact, in compliance with the target. The number of samples the agency would have to run would be considerable.

DR. MORRIS: It's a lot higher.

MR. TOMPKIN: Right. Now with regard to the baseline data, those tests were -- those baseline studies are important. They provide an important piece of data to our base. We understand. However, they're not really conducted in a practical manner for a

compliance program or for a processor's program. Cutting off tissue is really a cumbersome and perhaps even a risky approach to getting a good microbiological sample. There have to -- I think that as you proceed and go down this path you should consider alternatives that are more suitable to -- or more friendly, let's say, to sampling and testing, but still yet providing a good valid analytical sample that gives us the information we need.

MR. BILLY: Joe?

MR. POCIUS: I'm not sure what I can add to all that. The only other thing that I might though -- once you've gone through all the steps that Bruce has described and you had asked what empowerment or enforcement action, I believe, compliance and enforcement the agency might take, I mean if it becomes clear that failure is on the part of the plant the proposal has described that as a revocation of the HACCP program. Without a HACCP program there is no processing. Basically the plant shuts down. That's a high motivation not to try and cheat on a HACCP program. The other thing that a continual failure might indicate is that your performance standard wasn't properly set or in the case of a continually improving performance standard you finally hit -- you're so far down into the toe on that curve that it can never been hit. Someone earlier described that as sooner or later your performance standard will be zero and you can't hit zero. So everybody eventually will fail and that should be an indication that you hit the bottom.

MR. BILLY: Okay. Katie.

MS. HANNIGAN: Katie Hannigan with Farmland Foods. Very basic question. Why do you require both carcass and ground meat sampling?

MR. TAYLOR: There's something going on here because Tom and I were just saying that the one real important question we wanted to get out on the table was this issue of ground beef or ground meat -- you know -- because we proposed that the targets for pathogen reduction would apply both to carcasses in slaughter plants and to ground product and we would like some discussions of the pros and cons of that.

MS. HANNIGAN: Can you say why it was proposed that way though?

MR. TAYLOR: Well, I think the -- I mean the concept generally, and others can contribute -- you know -- was that this is a large component of fresh, raw, ready to cook supply of meat and poultry of the country and we would like, obviously, to have the confidence that we're reducing pathogen levels there. But we realize through the comments that there are -- you know -- very legitimate questions to -- you know -- have been raised about whether that's feasible, desirable, necessary, and certainly -- I mean once an area, the way it's been hit on in the comments very heavily, is in a plant that -- you know -- consists of a continuous operation where we're -- you know -- slaughtering and grinding in the same plant and someone earlier -- maybe it was Joe -- used the example of you could be in the mode of doing a test -- you know -- someone who goes from slaughter to finished package sausage in an hour -- I forget who said that -- but that if you're testing twenty -- Kim -- you could be testing twenty minutes apart and is that really a good -- I mean is that necessary, appropriate, helpful, so we do have some questions that have been raised by the comments about how we ought to apply -- you know -- a

pathogen reduction target specifically and perhaps also the fecal indicator -- you know -- process control testing for generic E. Coli. I mean the same questions might be asked. We would appreciate some discussion about that.

#4 MR. MAAS: In a plant such as mine where I'm strictly a further processor, I do know slaughter. I buy all -- I bring in boxed beef, I grind it, and form it. The only thing that I can do is to maintain the micro population. I can -- you know -- it would be my goal not to get it go -- not to let it get higher in the amount of time that it's inside of my plant. But I'm not sure that I have any means to reduce it. I mean I grind and form and sell raw so my goal inside my plant is to whatever the micro population of my raw materials that it doesn't increase but -- you know -- once again, my next question regarding the baseline -- you know -- I'm limited in what I can do and what I can't do. With regards to a baseline as it relates to my in-coming product, so as long as USDA stamp means that I -- you know -- that I'm grinding off of means that's the baseline or below or above, whichever you guys look at that, I cannot lower it. I can only do what I can to maintain the population when it's in my plant.

MR. BILLY: I have a question for you about that. Do you have specification for your raw material?

MR. MAAS: I just -- my specification is that it be USDA approved when it comes to me.

MR. BILLY: Even after the discussion the last couple days?

MR. MAAS: I'm sorry. I was being -- I'll be glad to answer your question. It's nice to hear people laugh on occasion.

MR. BILLY: I agree with that, particularly on Friday afternoon.

Have you considered that beyond reliance on the inspection mark giving where this is heading the possibility of having some sort of a specification that would allow you to do something about what your raw material is coming in the door?

MR. MAAS: I would probably rely on your specification. You understand that I rely on the USDA products that I buy that when they come in -- you know -- even with regards to -- in our city we have several further processors. I don't know why in Cincinnati but there's just a bunch of little companies that are -- I believe we have over twenty inspectors in just the greater Cincinnati area. But we actually had a positive 0157 at a guy much smaller than I am quite frankly -- you know -- he -- further processor -- just buys a few boxes of beef and grinds it up and makes patties out of it and the agency was directing -- you know -- random sampling. He got picked and came back positive. He discarded the load and everything else like that but I'm not sure that it was -- you know -- he got -- they were talking about involving the media in this whole mess and this guy had nothing to do with that -- you know -- from a practical standpoint so luckily they were able to keep it out of the media but -- you know -- that's processor's talk but other than that. So it was a touchy situation and so then I asked that question again. I'm a further processor. The meat that I get got's the USDA stamp on it. I cannot lower the micro count. I simply have no means to do that. I don't know have the couple million dollars it takes to put a stein up and in and the whole deal and I sell my products raw and do a good job at it and I sell a lot of it quite frankly and I'm not crying poor, I do well, but I depend on the products that I grind -- you know -- being

wholesome when they hit me and it's the only thing I can do. I don't mean to really to continue this but in case anybody really wonders why I keep hammering this why me thing is because I buy my meat frozen, I temp it to twenty, I grind it frozen, I grind it out frozen, I patty it frozen, it goes in a spiral and goes right back in the box. I mean I'm not worried about this a bit. Really. You understand? At least in that operation there's no way that I can do anything to -- you know -- cause a micro problem -- you know -- I am -- I don't mean to say that -- okay -- I don't mean to --

MR. BILLY: We'll talk later.

MR. MAAS: I'm sure there's lots of ways but in general -- you know -- I do what I can to decrease -- personally -- I mean this was not an accident. I intentionally developed a procedure that lowers my chance of problems. I have that flexibility and chose to follow that.

MR. BILLY: Angie?

MS. SIEMENS: Angie Siemens with Oscar Meyer. I'd like to go back to Katie's original bringing up the patties versus the carcass. It goes back to Ken's original message that I don't think there's one test that fits all programs so there's several of us in the industry that do a total flow through of carcasses into cooked product. I think there's some examples there that the testing -- if we choose -- and we've got some product that does go into a few raw products I believe we should have flexibility to have HACCP offers us to put that testing verification in where it best fits and in many of our occasions it may be at our ground turkey versus not as efficient for us to do all of our ground -- excuse me -- all of our carcasses where the majority of those are going to be cooked. So I encourage you to consider that

there is some -- what I would believe some flexibility in verification due to our specific product, plant, characteristics and that, again, one test doesn't fit -- you know -- all plants on that part.

I'd also like to go back to the compliance question that you had on Lee. I believe we should have some flexibility if a plant is moving towards trying to find out why you're not being verified within the limits of your E. Coli test we have a flexibility. I've done the same thing Jim has done -- worked my tail off trying to chase a bug and it just disappears and you have no reason -- you know -- to know why it did. They're creative creatures and it does take some time and that one test -- you know -- from our standpoint shouldn't put us in a non-compliance parameter and I don't know if it makes it very warm and fuzzy or very difficult just tell your inspectors what is at the point that that plant is not trying to comply with improvement or not trying to comply with improving your E. Coli position but, again, it's not an easy task when you're trying to chase micros down and figure out why a situation is occurring.

MR. BILLY: Paul?

MR. VINDERLINDE: My name is Paul Vinderlinde. I represent the CSI right from Australia. I just wanted to take up a point that Joe made when boxed beef comes into his plant he has no control over the quality. I just wondered what the agency -- are they planning on setting any baseline limits for pathogens in boxed beef? I mean because Australia exports somewhere in the region of twenty million cartons of boxed beef to this country. Australia will eventually have to comply with whatever the domestic market here comes up with.

MR. TAYLOR: And that's the easy answer to your question is

whatever standards and requirements we impose to domestic producers will apply to those who seek to export here. Yeah, I mean, our proposal really didn't apply to boxed products -- I mean didn't apply to pathogen targets to boxed products.

MR. VINDERLINDE: That's our main export product to the U.S. is boxed beef.

MR. TAYLOR: The equal or now equivalent system that you have would mean that if we have a pathogen reduction target, for example, for -- you know -- beef then the equivalent system in an exporting country would also have a pathogen reduction target with a similar compliance mechanism. I mean I'm just giving you the full answer.

MR. BILLY: See, the context of all this, what you're talking about is process control and verification process control and so the question about a particular product, if you will, boxed beef needs to be looked at in my mind in the context of where it's produced and what conditions it's being produced under and whether that process is under control and so that's why I was pausing to think about whether there is anything unique about boxed beef. I think the answer's no. I think that this about improving the safety of products and accomplishing that through process control.

MR. VINDERLINDE: So I mean if we're running under HACCP and showing control over carcass beef we wouldn't necessarily have to be testing boxed beef being exported as long as you're under a HACCP system.

MR. BILLY: I think if testing or part of your system of process control and verification --

MR. VINDERLINDE: I mean testing at this end. I mean we would

test it as part of quality control HACCP system.

MR. BILLY: Interesting.

MR. VINDERLINDE: Think about it. We can get on with the discussion. Thank you.

MR. TAYLOR: Good question. Thanks.

MR. BILLY: Good question. I don't know how to -- I don't have any -- anyone in line here so I think it's time for a break. Let's take a fifteen minute break.

(A brief recess was taken)

MR. BILLY: I think we can probably wrap up today's session pretty quickly. There's one last billet item that we haven't addressed yet and that's laboratory accreditation and at the scoping session -- I guess it was a couple of weeks ago -- we -- it was suggested that we add an item on laboratory accreditation under the section so I'd like to open the mike up for any discussion that people would like to have with regard to that question.

MS. DEWAAL: I have a question. -- -- frequency of testing? (microphone not hooked up)

MR. BILLY: Probably not in any detail. I think it -- in the context of what it would take to verify would be driven by the circumstances of the situation. But we can talk about that as well.

MS. DEWAAL: Well you proposed in your proposal one sample a day. Can you tell us what the current thinking of the Department is?

MR. BILLY: I think it would be fair to say that beyond the notion that we could consider that model as one option we acknowledge that there were -- you know -- as we said in the paper for today -- a number of suggestions about basing it on production -- or volume or

other bases that would accomplish the -- accomplish both a cost impact and a -- reduce the size of the windows in terms of what was proposed in the Register. We were looking at all of those options as part of the consideration of our current thinking on using E. Coli and using a pathogen targets for our verification. To be honest, our thinking has gone a lot beyond that at this stage. It will now, based on the discussions we had here today.

MS. DEWAAL: Will we be given an opportunity to hear your thinking maybe at the next round of meetings?

MR. BILLY: One of the -- one of the ways to deal with that would be to incorporate it into the discussions in terms of compliance, what would be expected of industry, what would be expected of us, and build it into that discussion.

MS. DEWAAL: Or as a separate discussion on that day?

MR. BILLY: Separate. Sure.

MS. DEWAAL: That would be fine.

MR. BILLY: Okay. Jim?

MR. HODGES: I just want to follow up a little bit on what was said before the break and even somewhat this morning. We had urged the agency to keep in mind that in any HACCP program has to be product and process and plant specific. I think that embodies the concept that we need some flexibility in these programs of where you do your microbiological testing and how much you do it and so forth. The examples have been put on the table. If you're a slaughter and you move all your product into cooked product that's an entirely different set of circumstances than one where you are producing all raw product for the marketplace. If you're producing product to go to

export that has limitations on certain anti-microbial treatments as an example. That's another set of circumstances so the flexibility that has to be built in the system is what the industry has the original concept is HACCP programs are not -- are not identical. Consequently, the verification or validation of those programs is not all the same. If you're -- I would contend that, as I said before lunch, that if there's a performance standard to be established that performance standard and most appropriately is E. Coli or other kinds of indicator organisms that is by all accounts the best measurement of process control and clearly through your baseline studies over the course of a period of time you can establish some guidelines for regulatory consideration on E. Coli -- generic E. Coli and what that -- Mr. Taylor posed a question of what kind of regulatory action would you take. Well, the first thing is that you need to be sure that you have enough samples in your sampling plan to have some confidence that there is -- that this plant is producing at some level that is not -- not in accordance with established standards. Secondly, I would suggest that one of the regulatory actions that would be most appropriate is if you have these technical teams that do an audit of that plant would be audit of that HACCP program would be quite appropriate. It still seems to me that we're going to have an awfully difficult time of establishing a performance standard based on pathogens for all of the reasons that we've stated here. Clearly, the baseline numbers can be used as a measurement of the success of your regulatory programs, they can be measured as a success or failure, if you will, of the -- of the general nature of whether the industry is improving or not but on a plant specific basis there's way

too much variability in those numbers to get very close to a regulatory standard. You've got to look at the very dynamic nature of HACCP and how the process is intended to be an involving and improving process and under those kinds of conditions the appropriate regulatory action is to basically say is that plan operating as desired. It's very, very difficult for me and I think you heard from most people in the industry it's very, very difficult for us to envision a system where you have pathogen numbers that by default become an invalidation or validation, either way you want to look at it, of the HACCP program itself. Indicator organisms is the way to go in our opinion.

MR. MARSDEN: Tom, can I address this issue?

MR. BILLY: Sure.

DR. MARSDEN: Jim Marsden with Kansas State University. As I understand it, FSIS has an accreditation program for chemistry laboratories but not for microbiology. They recognize particular methods on the microbiology side and it seems to me as we get into what probably will result in a much greater level of industry microbiological testing the agency should consider an accreditation program for microbiological laboratories as well. It would give companies some comfort when they go to a laboratory that they're going to get proper results and so on and also in my view would add to the credibility of any data coming out of independent laboratories if they were backed up by this type of accreditation program.

MR. BILLY: Dane.

MR. BERNARD: Thank you. I was curious -- I was at the scoping meeting when this topic came up and it was kind of toward the end of

the day but not being in disagreement that certification is a good idea. Are we talking about something different than what you already do? I mean we have laboratories that are, including our's, who are -- you know -- accredited through USDA to run USDA -- to run official samples and are we talking about something in addition to that or is that what the program envisioned?

MR. BILLY: I think it is important to make it clear that in terms of what the we are talking about we stated in the proposal that it wasn't our plan to have an accreditation program but we're open to comment since it was suggested at the scoping session that this item was important to put on the table for discussion. We've done that. But that should not be interpreted as necessarily a change in our position. We are certainly open to comment and suggestion in this area.

MR. BERNARD: If I could just talk to the comment then. I think that having officially recognized laboratories as you do now should be sufficient.

MR. BILLY: Okay. Katie?

MS. HANNIGAN: Katie Hannigan, Farmland Foods. I guess our lab is one of your recognized labs and I don't see the need for that for everybody in the industry if indeed the plants are going to be doing E. Coli testing and not salmonella testing. I don't -- the E. Coli testing is pretty straightforward. It's simple. I don't see that need unless we're talking about them having to do the salmonella test.

MR. TOMPKIN: I'd like to comment on that also. I agree with what Katie has just said. It was different if you had a salmonella -- if you're testing for pathogen that's a different issue but the beauty

of running E. Coli is that it can be done within the plant and it means you're going to be certifying or accrediting laboratories in all of these plants and that's -- we want to encourage testing by plants. That way they can exercise -- they can develop the data themselves and then they're in control. That's important that they generate their own data and it should be encouraged. That would be a real roadblock to that.

MR. MARSDEN: Can I comment again then?

MR. BILLY: Sure.

MR. MARSDEN: Bruce and Katie, what do you think about accreditation for pathogen testing though? That's really what I'm addressing. Not plant E. Coli testing. I agree with you there but for pathogen testing USDA currently recognizes the capability of a laboratory to do that kind of testing and I think that should absolutely continue in my view.

MS. HANNIGAN: Yeah, I agree with that. I mean that's current program they have now. I just don't want to see accrediting laboratories for E. Coli testing.

MR. MARSDEN: And I agree with that also.

MR. TOMPKIN: And I agree with what Katie has said.

MR. BILLY: Caroline, it's up to you.

MS. DEWAAL: I want to offer my agreement with everything everyone said before me but -- but there's a but.

MR. BILLY: Now I want to make sure I understand. Is that for the previous two days?

MS. DEWAAL: We raised the issue of laboratory accreditation in our comments and I think in listening to this discussion I think we

would agree that E. Coli testing is simpler and probably can be done in the plants. However, the agency should consider recommending a specific testing methodology. Let's make sure that the tests are comparable, that the tests are accurate, that there are some minimum standards for what tests are used for the E. Coli. Otherwise, we're going to end up with a mess.

MR. BILLY: Any thoughts on that?

MR. TOMPKIN: Yeah, Tom. The expert panel from the Philadelphia meeting actually did over some guidance in that direction. While those particular recommendations may not be the final ones but at least that was the direction. Yes, there should be some. If we're going to have a national program we have to have an agreed upon method of sampling and analysis by species of animal or if ground products are included those products also.

MR. BILLY: Okay. Any other thoughts about laboratory accreditation by anyone? Okay.

That pretty well completes the program. I wanted to first ask our agency folks if there were any other questions that they had that they would like some input on in terms of what we covered today? Okay. And how about everyone else? Dane?

MR. BERNARD: Very quickly. Thank you. There was a couple of items that were discussed today and yesterday where in specific the request for data on the -- that the agency could look at and try to recognize some appropriate baselines and things like that. As I said yesterday when we were talking about generics, I think it would be our preference to have that process not be a closed door process. You've got the National Advisory Committee available where the

agency can certainly do a digest of the data but I think in looking at what is an acceptable baseline for whatever criterion it is we'd like to see that process be a little bit open so that -- you know -- we build some consensus behind these decisions so that whenever we get to the point of having a rule we don't run into these big debates over the specifics of the number. I think we can do some consensus building on the way if we just open the process up a little bit. And the same with the generic plans that are going to be worked on. I know there's plans to peer review this but I would ask that as soon as the agency has them in the kind of shape to be shared to where you're a bit comfortable with them, until we find out what kind of problems people might have with them, before we get to that deadline of saying this is an acceptable HACCP plan to the agency let's try to build some consensus with those and try to do that in a bit more of an open situation. Thanks.

MR. BILLY: Lee?

MR. JAN: I had one -- one question that still is still not fully answered and it deals --

MR. BILLY: You've done pretty well there.

MR. JAN: Yes I have.

MR. BILLY: Sorry.

MR. JAN: But it has -- it deals with the current thinking on this agency testing for salmonella. Is the current thinking to test -- the agency to test salmonella daily in each plant or at some frequency in each plant or to test what the industry -- kind of like on the national let's do monitoring program -- where you do random across the industry to see?

MR. TAYLOR: The current thinking does not include an answer to that. The current thinking is that the agency would have to maintain a testing activity and an overall compliance monitoring activity sufficient to provide an incentive for plants to actually work to achieve the target and to give us confidence that we know who's achieving it and who's not and that doesn't necessarily mean daily sampling and, in fact, it probably -- there probably are better ways than the single sample on a daily basis for doing that. Perhaps there are. And so we don't -- again, you saw our performance standard but how we would figure out to do that is a work in progress and we just don't know the answer. We welcome suggestions during the next -- you know -- few weeks of an open comment period.

DR. MORRIS: Mike, I think one thing we can say and I think you've said, just to re-emphasize, is the idea that there would be individual plant accountability.

MR. TAYLOR: Right.

DR. MORRIS: So we would not be looking at an industry-wide model. We would be looking at a model which in some way factored in plant accountability so we would know this plant is not meeting our targets.

MR. JAN: So to have usable data there you're talking about the agency doing a significant amount of salmonella testing.

MR. TAYLOR: That's fair to say.

MR. JAN: And that means mistakes. Make room in your lab for our samples.

MR. TAYLOR: The point it pretty well taken.

MR. BILLY: Unless there are things we can identify that you

could stop doing that would save the money to do the lab testing.

MR. JAN: And there are. I mean economic testing, we could stop doing those. But I don't think we do enough economic testing to make up the cost that would be for doing the salmonella testing.

MR. TAYLOR: We have noted the issue. You have raised a very important question and it will definitely be part of our thought processes. Thank you.

MR. BILLY: Barry? Barry?

MR. MARSHALL: Thank you, Mr. Chairman. I think Paul Vinderlinde from CSIR Australia brought up a topic just before smoke out. I thought it was appropriate. It's probably something I should bring up and he threw in the question even though it's actually going to be addressed at the next series of meetings but I really want to put something to the Administration just so that they're in a position to actually answer the question we're going to ask when it comes about and that's about -- there's a section there about international considerations -- export issues and import issues. And with regard to that, we would -- we, meaning New Zealand, and I'm sure Australia and everyone else for that matter, we understand that we need to meet the same standards that are addressed locally here in this country and so we will be obviously putting in place systems to meet the requirements so we actually get to the end point that everyone's satisfied. And this, of course, means not only verifying or validating and verifying the systems amongst others but a whole range of other things. With the philosophy of certainly international programs or FSIS of actually targeting a hundred percent of consignments coming in and looking to make sure that the products -- you know -- the

documentation's right -- we would be more than concerned if imported product was going to be targeted and tested. We wouldn't mind if it was on a vague random base or infrequent random bases but it was going to be done on a consistent basis we wouldn't be happy at all simply because that would imply that if our systems are accepted in the exporting country, we're meeting all the requirements, have processes in place giving everyone the confidence, then we would expect that the meat that is produced to be treated to the same manner that local meat is produced and that once a plant has had its systems approved and it's showing it's competent and it's producing this product it's not being tested further down the track and action taken against it. And the same thing would probably apply that because we are an exporter and we do the same thing for meat going on the local market I assume that the same standards would apply for export meat regardless of what the requirements are of the importing country which this country exports do. So those are some issues that I would like you to perhaps think about and I'll ask them again in a couple of weeks. Thanks.

MR. BILLY: We, in fact, plan to have a paper that addresses this international -- these international aspects. Dennis?

MR. JOHNSON: Dennis Johnson, Olson, Frank, and Weda. It's not really a comment or even a question. It's just a request for a favor. I think I've been taking fairly good notes throughout all this but there's still a lot of current thinking which is being thought on. And I was wondering before we take up compliance the last day of these sessions if it would be possible to have another briefing paper perhaps to set out in a little more detail your compliance in terms of

the testing requirements. We really would appreciate it.

MR. TAYLOR: We'll think about it. We'll try. We want to come back to some of these issues and if it's possible and will be helpful we'll try to do that but let's just see how it goes next few days.

MR. JOHNSON: Like I say, we'd appreciate it.

MR. TAYLOR: Reasonable request.

MR. BILLY: Okay. Caroline?

MS. DEWAAL: One more question. What's your current thinking on when you will have the final rule?

MR. TAYLOR: Someone said we had a deadline of December 31st which sounds good to me -- you know -- let me just say that's been our goal and remains our goal and we're working -- I think we have witnesses who will corroborate we're working very hard to achieve that and my personal view is that we're not at the end quite yet so I won't make my concluding remarks but I think this process actually will help us get there by then and so I'm increasingly -- I mean I remain very optimistic we will achieve that. I wonder if the L&B staff are still in the room. They have a certain contribution to make to the time.

MS. DEWAAL: I hope it does but I hope this process doesn't delay the rule getting out.

MR. BILLY: Lou?

MR. GAST: Lou Gast. Tom, would you care to speculate on when the issue papers for the next session will be available?

MR. BILLY: No, I don't care.

MR. GAST: May I rephrase? Would you speculate on when they will be available?

MR. BILLY: I think I'll let Mr. Taylor here handle that.

MR. TAYLOR: Our goal is to have them available prior to the next meeting as we did this time. They're just in time papers.

MR. BILLY: I can say this, this meetings are well over a week away. I can say this, that the agency -- there are drafts of those papers and that wasn't true a week ago in terms of preparing for this week so I would take that as a good sign.

MR. MAAS: I wonder if they would be available at the AMI?

MR. BILLY: It's possible. There are several of us heading in that direction. If they're available we can --

MR. MAAS: -- -- (no microphone).

MR. BILLY: That's a good point. And we do have a distribution system for all the interest groups so -- you know -- we're prepared to give them out if we can get them ready and cleared.

All right. I think we're finished. I'd like to thank everyone very much. You want to make a wrap? Okay. Mike.

MR. TAYLOR: I just want to thank everyone who's participated. This is -- three days has been very, very valuable for us and the effort that everybody has put into it I personally greatly appreciate both from our agency and from all of the groups that have been -- individuals who have been -- who have been here. We have duly noted those of you who have stayed till the end and there will be some reward. It may come in the next life but I'm sure that there will be a reward for having stayed till the end. We appreciate it. Have a good weekend.

MR. BILLY: Thanks.

(Whereupon, at 4:28 p.m., the meeting was concluded.)

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