UNITED STATES
DEPARTMENT OF AGRICULTURE

In the Matter of:	)
	)
NATIONAL ADVISORY COMMITTEE	)
ON MEAT AND POULTRY	)
INSPECTION MEETING	)
	)
HAACP SYSTEMS IN-DEPTH	)
VERIFICATION REVIEW	)
	)
RESOURCE ALLOCATION STANDING	)
SUB-COMMITTEE	)

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Wednesday,
November 3, 1999

Room 2331
Quality Hotel
1202 North Courthouse Road
Arlington, Virginia

The hearing in the above-entitled matter was convened, pursuant to notice, at 7:04 p.m.

APPEARANCES:

LEE JAN, CHAIRPERSON
Food Policy Institute
Consumer Federal Of America

MAGDI ABADIR
Cuisine Solutions

CHERYL HALL
Zacky Farms, California

ROSEMARY MUCKLOW
National Meat Association, California

DONNA RICHARDSON
Howard University Cancer Center

JUDITH RIGGINS

CAROLINE SMITH DeWAAL

P R O C E E D I N G S

(7:04 p.m.)

CHAIRMAN JAN: Our charge is -- I'm not sure. The only thing that I heard that they really want -- I'm sure we want to hear everybody's concern. But the one charge that I heard was for us to consider other sources besides this document that the National Advisory Committee on Microbiological Criteria for Foods.

And that is something that probably we won't be able to come up here. It's probably something that -- you know, unless somebody knows of some other criteria or of some other resources to get information. That was the only charge other than, you know, our discussions and your input.

And then also, we had a request from one of the members of the public asking that we look at the process. And that may be worth discussing, the process. I doubt that anyone had the chance to go through this with any detail. We kind of got it dropped on us today.

I can say from my perspective, I do believe there is a need for some tool or some instruction to use to evaluate HAACP plans because regulators, like industry, it's all new to them. It is all new. And the basic -- the basic -- and it sounded again today what she said, the basic is just are the elements there.

And that doesn't necessarily make a HAACP plan

effective. So we are not going to know whether it is going to be effective. We do need some kind of tool. So anyway, let me just open it up and get -- let's get comments on what we -- what everybody is thinking.

MS. MUCKLOW: Well, as I said in the public meeting, and I feel very strongly about this, one of the things we didn't do right the first time was to have the proper interactive communication between those who are training the industry on HAACP and the Agency's regulatory HAACP training.

And that has contributed to more misunderstandings and confusions and downright adversarial conditions. And HAACP shouldn't be introduced and move forward in a very adversarial relationship. It should be moving forward in a cooperative relationship.

FSIS has been supportive and involved with the International HAACP Alliance that was formed in 1994 and that has developed accredited programs and is now working on audit programs and developing an accreditation for the auditing of HAACP programs.

So I think this gives us a new opportunity to bring the professionals in the industry, teachers, the International HAACP Alliance, the people who were there today like the Dane Bernards and the Bob Savages, together with the leaders of the Agency to talk about HAACP auditing

and to embrace the best ideas of both parties.

I understand that the Agency has a regulatory responsibility to do certain things from a regulatory perspective. But if this is going to be an in-depth verification of a HAACP program, then I think we have a chance to write a different chapter and to write a cooperative chapter between the industry, the state agencies, the international community and Food Safety Inspection Service, and the trainers who train the industry personnel in HAACP, to really come together and have some kind of a working group to work this out.

The Agency is always going to reserve positions for regulatory HAACP. But a lot of this kind of stuff needs to deal with basic HAACP itself and how it is functioning in the industry. And I think that's a step -- I didn't hear any discussion of that today. And Judy can tell us whether there has been any discussion of sitting down and working it through with the industry professionals. I just feel very strongly about this.

MS. RIGGINS: No, we haven't had any -- we are not ruling it out. But I am not aware of any discussions that we have had thus far to have, you know, an interactive industry and agency approach. But that doesn't mean we -- you know, we can't have a meeting on --

THE COURT REPORTER: Excuse me. I am sorry for

interrupting. But I need you to use a microphone.

MS. RIGGINS: No. That doesn't mean that we can't have it. I think this was our first attempt, understanding that we in the final rule did state that we -- our commitment to conduct in-depth reviews. This was our first attempt at articulating what the substance of that review would be. But it doesn't rule out, you know, the opportunity to do that.

I am not sure if you would want it to be part of the technical conferences that we have begun. We had one in Omaha during the summer -- I guess it was actually early fall. And we plan to have a follow-up conference. But, I mean, what the venue would be, we can decide. But there is nothing that says no, we won't have it.

MS. MUCKLOW: Well, up until this point, Jeannie Axtell -- but she -- since she changed her position, she was no longer the designated FSIS person to participate at the HAACP Alliance. I think it is Barbara Masters now from the Tech Center. And so, again, I just think it is absolutely critical that we write a different cooperative effort for this kind of verification process than we did in implementing HAACP.

And I am sorry we didn't fight harder when implementing. We should have done a lot of things jointly. On think on this, it is essential that we involve the

people who are truly the HAACP experts.

I mean, I -- today Bob Savage and Dane Bernard, and I am sure there were others in the room, I didn't notice, who have that expertise to really talk about verification. I just think it is absolutely critical.

CHAIRMAN JAN: Did you have --

MR. ABADIR: Yes. My comments here are coming from actual experience of going through several HAACP plans and going through three or four times ordered by FDA which is in-depth research audit of HAACP plans. What the interesting thing about this type of a document, this is very interesting. And I am just checking the points here, not talking about anything, but checking the points for this. So the input is welcome from definitely anyone who has expertise.

But what I see initially in this document, it is covering everything in steps, which is good as an initial document here. But the important thing is the timing which has been addressed by some people from the audience here, the timing of this. And you have addressed it also in that declaration.

If a notification is given to plants on that, that is very important. That must be happening because FDA, when it comes to my plant, it works two or three days. Three days I have all quality control. Our management is just

answering questions which disturbs our operations tremendously for a whole week. It is just nature.

Here you have an inspector in charge in that facility who can prepare and come up with a lot of this information. So it becomes two hours or three hours' work with all the information on the table. Everything has been prepared in advance which is very necessary in this process.

I think the content is acceptable as an initial start-up document. But the issue of timing and notification to plants from this initiative is very important.

And I would say if they are talking about four or five people coming to the plant for a complete inspection, for in-depth verification, that they want all the documentation and verification and shipments reviewed and everything which are in different locations and facilities and different coordination. That's major. This is one point I want to see.

And the other issue that was very helpful and I said I went through this with several -- three or four plants in terms of the actual verification benefits. The benefits come up. You are dealing with someone who is really experienced with what you need to answer. For example, the HAACP analysis, we evaluate it.

But what can we wait for years? They have a different perspective. That is good. They are not

requiring us, but they are telling us in other areas of the industry, this is how you can look at this issue.

In others, for example, sausage companies, this is what they are looking at. This is important, distinctive. We are putting it as notes for you to look at. So that it makes more than the expertise of just coming from the IIC or the inspector seeing what you are talking about. That's why these people, which will be raised also in the meeting tonight, they have to have someone who has really a technical background meaning this computer kind of audit. If you are having just the district manager here and the IIC, we are not doing anything.

MS. HALL: I think it is a very good point. Those are very good points that you brought up. And I would like to add to that a bit. It is that we are supposed to be in a cooperative situation. It is that we have many, many different types of testing going on that both the plant is expected to do and the USDA is doing. So there are a lot of safeguards in effect already.

This in-depth verification should be a cooperative get-together; let's sit down and talk about your HAACP program so we can see if you have any problems with it. Certainly, the format is fine. But the presentation and the way that it is implemented is a whole different story.

If this is a surprise, we are going to walk into

your plant and we want all the records laying on the table and we want somebody sitting in that chair to answer the questions, if that attitude is brought into a plant, industry does not deserve that.

At this point, they have cooperated all along the way. They have all of these records in effect and they can present them. But that is not the attitude that should be presented to industry, that we want it now. Industry certainly would like the help of USDA to confirm that everything that they have been doing is correct and is along the lines expected. That's fine.

Now, if you have a plant that is way out of line, that plant already knows it anyhow. But that could be a different situation in that this is a plant that we think is not in compliance and they deserve maybe a different type of approach. But I hope at least on the first round of visits to plants, they would -- USDA/FSIS would consider the approach that we are here to mutually observe your HAACP program and your records to make sure; not an I've got you, we want it on demand situation.

CHAIRMAN JAN: What about --

MS. MUCKLOW: Yes, I think that's right.

CHAIRMAN JAN: What about this technical committee that you said -- technical meeting that was in May or --

MS. RIGGINS: Yes, it was --

CHAIRMAN JAN: Who was invited? Was that a public meeting or --

MS. RIGGINS: It was a public meeting. And there were a number of representatives from industry there. And the agenda was assembled or put together by a committee that was made up of industry and FSIS people. And committees -- the committees or the panels that were assembled for the -- you know, for the different areas of discussion consisted of people from the industry and people from the Tech Center and also headquarters of FSIS.

But for the most part, the headquarters people were there basically just to listen and, you know, just to hear the issues. And the Tech Center really took the lead on this. Paul Thompson --

CHAIRMAN JAN: Regarding this particular -- that was the whole meeting, about this in-depth --

MS. RIGGINS: Well, no. Some of the issues that are inherent or implicit in this -- in the substance of this in-depth review, especially in the checklist, are issues that were discussed at the technical conference. But we have a whole set of questions, follow-up questions and issues that we have made a commitment to follow through on.

So there will be another meeting to get -- you know, at least to come back with our responses, at least our thinking on those issues. Many of them are things that we

are having to think through because they hadn't -- we hadn't encountered them before --

CHAIRMAN JAN: But I think --

MS. RIGGINS: -- you know, because the complexities of HAACP now are really beginning to emerge. So a lot of them we had to go back and do our homework on and think through. And that's what we will be coming back to -- you know, to present to the --

MS. MUCKLOW: Okay. Judy, was that the technical conference in Omaha?

MS. RIGGINS: Yes.

MS. MUCKLOW: So that was the first and there is another one coming up in December.

MS. RIGGINS: And we are going to have another one. And --

MS. MUCKLOW: Could you possibly consider having as an adjunct to the December technical conference sort of a follow-up with the representatives of the HAACP Alliance, with Dr. Harris and other designated people who are, you know, the trainer types, the Dane Bernards and Bob Savages, the Joe Blairs, the other people who do the training of HAACP people, to sit down with all of them and look at this kind of a document?

MS. RIGGINS: Review this? I don't think that that would be a problem, no. I just --

CHAIRMAN JAN: I think that should be a recommendation of this sub-committee.

MS. MUCKLOW: Let's make that as a recommendation.

MS. RIGGINS: We have to set it up, you know, so people can get there.

MS. MUCKLOW: Yes. Well, I think most of those people are going to be at that -- I am not going to being I am a political scientist. But I have somebody who is a scientist going to that meeting. My technical person is going to that meeting. But I am sure that the Savages and the Dane Bernards and otherwise -- they were both there today, so I keep thinking of them. But there are others in that category that are doing the training these days and who all qualify as train the trainers and so on.

But I do think it is terribly important that the Agency work with the HAACP Alliance because they are bringing in expertise not only from the United States, but internationally. They are the International HAACP Alliance.

CHAIRMAN JAN: Yes. And it is critical I think that the tool that is used to verify a HAACP plan is one that is developed or at least has got the insight of those people. And it is not all regulatory. And it is not all industry. And I think these people are going to have a good blend. Their concern is food safety.

They are not going to be concerned about what are

the industry's concerns. They are not going to be -- they are not going to have the got-you attitude I think. So I think it is critical that those type of people are there to look at this.

I mean, I welcome -- I was concerned for a long time because how in my eyes a regulator is supposed to know if the hazard analysis is a good hazard analysis. I can look at a hazard analysis and see, "Did you ask the questions?" But what I am supposed to find out then, you know, like came out today. I've never killed anybody or I've never had anybody get sick. Well, that's not in my opinion acceptable.

We need someone though that is an expert in that field to know what are the appropriate questions, what are the appropriate documents that we as regulators need to ask for. And at the same time, the industry needs to have and to be more -- even from a -- getting away from being regulated from a food safety and protecting their customers so they live another day so they can buy some more product.

So what question should they be asking, but it needs to come I think from that neutral ground. And I think that would be --

MS. MUCKLOW: It has to be a respected document.

CHAIRMAN JAN: Right.

MS. MUCKLOW: And for that, it has to be a known

quantity. Usually what the Agency does with stuff like this is they will write a directive and they will say this is -- you know, and they will attach it in its form. And if in a year -- you know, I understand your need for fluidity. If in six months or a year it needs revision, then it becomes Revision 1.

I mean, that is the way the system operates because you are a regulatory agency. And the actions that you can take have the potential for enforcement sanctions against those companies that are visited. So I think, you know, it needs to be a finalized directive that says, "This is how we are going to verify it."

But I do think it would be really, really helpful if it can be developed in a cooperative environment with people who are knowledgeable, people who understand and know HAACP. Because, indeed, we are the world leaders. And the other countries may follow us.

CHAIRMAN JAN: You have a different perspective I would think than the rest of us. I guess you are more of a -- in research and more of a consumer-type background.

MS. RIGGINS: Yes, a consumer background. And unfortunately, we didn't get these materials ahead of time so that --

CHAIRMAN JAN: Right. We discussed that.

MS. RIGGINS: -- I know a lot less than you guys.

MS. MUCKLOW: You will learn. You are a quick learner.

CHAIRMAN JAN: That's a good point.

MS. RIGGINS: Yes, I am.

MS. HALL: This is a very complicated set of rules. And it was prepared in June. We didn't receive it to even look it over. It's very difficult for us to assist.

CHAIRMAN JAN: We need a little heads up if we're going to be a useful committee.

MS. HALL: Yes, to be able to make recommendations like that.

MR. ABADIR: One of the points also that I could mention and maybe I would like to stress on them again here is that --

THE COURT REPORTER: Excuse me. I can't hear you I'm sorry.

MR. ABADIR: Oh, okay. One of the important issues is that you need to see the results of this as soon as possible, either at the same time of the audit. You have presented that it is important to show how you are doing so that you can change or you can do a modification. If you are taking this report and sending us a report after industry -- four or five weeks the process has been changed, maybe the products have been discontinued already. So we need to be --

MS. MUCKLOW: Don't let him in.

CHAIRMAN JAN: That's a good point. And that brings us to what was -- talking about process.

MS. SMITH DeWAAL: A public meeting but they lock the doors.

CHAIRMAN JAN: We want to select our public.

MS. SMITH DeWAAL: Well, I am a member of the committee, so --

MS. MUCKLOW: Welcome.

MS. SMITH DeWAAL: Thanks.

CHAIRMAN JAN: Good to see you.

MS. MUCKLOW: Don't worry, Caroline. I have been told my big head was in the way of the board and a few other less prominent things.

CHAIRMAN JAN: Okay. So now we are finished with our work. Are you all ready to go home?

MS. SMITH DeWAAL: All right.

AUDIENCE MEMBER: I am writing things down. So if you could every now and then just check, see if what I wrote down captures what you said. And if not, let's get it where it captures a little bit better what you said.

MS. HALL: Well, I would say about this that the industry has asked for and did welcome at any time a critique of their HAACP plan. They have never been opposed to that. But they just don't want it to be big surprise

with a regulatory -- and then a penalty maybe of some sort attached to it if it's not correct. But they have no problem with HAACP plans being checked. Right?

MS. MUCKLOW: Yes. We are all in this and learning together.

MS. HALL: Yes.

CHAIRMAN JAN: And what Magdi was talking about is part of the process. And maybe we should recommend a process which includes what you are talking about, an exit conference, even at least a preliminary exit conference when the review is done with a -- maybe a more formal one within some specified period of time that is reasonable, within two weeks or a week or -- to put all this data together.

But I think the -- if you have a tool like this, you go through that tool. And it seems to me that when you are through with it, you should be able to get some answers or give an impression; maybe not give a formal report, but give an impression of the problems that you see.

This thing, I did look at it enough that it says when you do the system review, "Note actual non-conformance." So you are going to have notes if you have identified a non-conformance. So those should be shared I think immediately or when you are through, whether this is a two-day deal or one-day deal. I don't know how long this will take, you know. You all have done some or --

MS. RIGGINS: It depends on how long -- or how many processes the plant has, how many products they make. It will vary depending on how -- you know, how simple or how complex --

MS. MUCKLOW: They're not going to pick you up on that. They are going to want to hear what you are saying, Judy.

MS. RIGGINS: Did you hear me?

THE COURT REPORTER: It's extremely hard to hear you.

MS. RIGGINS: Oh, I'm sorry. No, I said it will hinge on the types of processes that the company is using, the types of products that they are making. And each company will vary depending on the size, you know, how many lines they have -- how many product lines they have. So it may -- you know, it could take two days. It could take two weeks. It just depends on how large and how complex it is.

CHAIRMAN JAN: Yes.

MS. MUCKLOW: And as part of the formal record, I think a company after they have had this exit discussion may write a report that should be included with the document in the formal record because this becomes a regulatory record. It is accessible under Freedom of Information.

You know, there may be proprietary things that can be deleted. But I don't have any doubt everything else is

in the fish bowl. This will be, too.

And, therefore, the company should have a right to raise any points of difference that they may have within X number of days, like seven or ten days following. And the document will not be available publicly until it is -- that condition is met because there are going to be differences of opinion over how things all operate. And it is part of the process we are going through.

MS. SMITH DeWAAL: Just to put my two cents in, I can see from the discussion so far that many of our industry colleagues are very concerned to make this a highly cooperative effort. But I guess my question here is how do we make sure it is an arms-length effort, as well; that the --

MS. HALL: Well, I guess the group that --

MS. SMITH DeWAAL: May I finish?

MS. HALL: Sure.

MS. SMITH DeWAAL: -- that the inspectors or the people doing the evaluation are doing a fair evaluation. And I notice Jan talked about how do we know if it is a good hazard analysis and the fact that the Agency needs to be sending out experts to do this work.

And I think that it has got -- the cooperation is good and protecting -- you know, making sure all the industry's concerns about it are captured in the record is

fine. But that it's got to be an arm's-length evaluation of the HAACP system done by people who are -- really want to see the HAACP system work and are not worried about, you know, how they are getting along with the companies.

MS. HALL: Well, I want to say -- and it is my turn, please. I would have to say that we assume since the group is supposed to be coming in from the outside, from the Technical Center, that it would be at arm's length; that they wouldn't have any desire to please the industry or to -- their whole purpose in being there is to evaluate the system. So I don't know why you would have a concern for that.

MS. SMITH DeWAAL: Well, that's good. Cheryl thinks their whole purpose in being there is to evaluate the system. That's good.

MS. HALL: So I don't know why you would be concerned about that.

MS. SMITH DeWAAL: I just thought you wanted them to sit down and talk. And they don't need surprises and stuff like that.

MS. HALL: I think -- yes, I'm sorry you missed that part of the conversation.

MS. SMITH DeWAAL: I am, too.

MS. HALL: But I think that when this particular program started off, the industry was very willing to go

along and support whatever the Agency needed. At this point, the first visit through -- I think that we have asked before for the FSIS to evaluate our HAACP program, to assist us to get it as to be correct for them.

And now to all of a sudden turn around and say, "But we are going to come in and nail you on this", is the wrong approach. The first time through, they should come in, go through all these plans, all these questions, and make sure that we are in order.

Maybe we've missed something. We shouldn't be penalized for it. We are trying our best. And we want to cooperate. The first time through -- okay, after that if you want to come in and look at it at random, that is fine and dandy.

But don't the first time out of the box just come in and surprise the plant and say, "Okay, we want your papers on the table; we want them all in order; and we want a person in that chair to answer the questions," because we have all kind of verification processes going on, all kind of testing going on. And to say that the HAACP plan is the main problem with the program would be incorrect at this point I think. So do you see where I am coming from?

MS. SMITH DeWAAL: Well, I don't understand when you say the HAACP plan -- I mean, what if they haven't identified a known hazard? What if they haven't -- I mean,

we really need people who can go in and --

MS. HALL: That's right.

MS. SMITH DeWAAL: -- and evaluate --

MS. HALL: That's right.

MS. SMITH DeWAAL: -- with the purpose being to get the HAACP plan right.

MS. HALL: That's right. Okay. Very good. That's right. Not a surprise. Not a penalty. Cooperative --

MS. SMITH DeWAAL: We want the companies to get the plan right.

MS. HALL: That's right. So we have asked for in the past for people to come in from FSIS and evaluate people's HAACP plans. We ask for any kind of assistance in developing those plans. And so certainly at this point, we would have no problem with them looking over, going through these questions, this format, evaluating it.

But we don't need a penalty or a surprise at this point. In the future, if that's what you want or if you have a plant that is out of standard and is known to have a problem, if you want to do a surprise on them, that's a different issue.

MS. SMITH DeWAAL: So what you are saying is that it shouldn't be an enforcement -- it shouldn't be part of an enforcement action at this point. It should be an

evaluation tool.

MS. HALL: Exactly.

CHAIRMAN JAN: I think that --

MS. HALL: We are at the same goal, right?

CHAIRMAN JAN: I would have to maybe tenor that just a little bit because, first off, when HAACP goes into effect, the HAACP plan has to be effective. Now, that's not to say that everyone is going to make it perfect the first time.

But if you wait until you get a review under this process -- and we heard maybe a dozen the first year and maybe 100 or hundreds the second year. And we've got, what, 5,000 plants out there. Then if you wait for this process, I will probably be not only retired, but probably dead before everybody has a HAACP plan working. So --

MS. HALL: Or your grandchildren will be in trouble later on.

MS. MUCKLOW: Hopefully they all will be working and all is correct.

CHAIRMAN JAN: Well, that's what I'm saying. But if there is a deficiency -- for example, I think this should be looked at as the new review. The review team came from Lawrence, Kansas or wherever they came from and they looked at structure and they looked at, you know, was that wall pink because this month's color is pink or whatever.

And now we are not going to worry about whether the color of that wall is right. We are going to look at food safety issues, direct product contamination, SSOP; is the HAACP preventing or eliminating hazards. We do this with this new system. So that is the new review tool.

And so just like in reviews, the plant is operating in the best of their ability and trying to comply. And we expect that they are complying, but we find out through this process that the plant didn't do their job and didn't do the proper hazard analysis.

And, further, the inspector just signed off that, yes, they got the basics and it's one of those that never likes to write NRs. You know, there are going to be some inspectors like that, too. So even in the plant, whether we have an ineffective inspector -- if we will still have some of those after this -- we need in those cases to take that action, whatever that may be. And that may be a plan.

I don't know, I'm not saying that we would shut you down because if you were doing it this way for two years and nobody got sick, maybe not shut them down, but get a strict plan. Okay.

Do you have it down analysis and get a growth plan that is a strict six weeks or 90-day or whatever it takes to get that plan back on track; not to say, "Well, industry, because we weren't here before, just get your act straight.

Next time we come by, we are going to really mean business. If you didn't like our warning this time, wait until you get our next warning, you know."

MS. RICHARDSON: And if you're talking about process -- and I'm not familiar with HAACP. But I am familiar with HCFA surveys and also NIH research audits in which -- and they revised nursing home regulations several years ago. And they had to adjust to a new claim.

And when HCFA comes in, unless they have received a complaint about patient care, they say, "In the month of November, we are coming in to see you. It will probably be the second week." And so people know. And it's just like with hospitals.

You know when JCHO is coming. And, yes, everybody scurries around to get ready for them. But they still come in and they can -- and they go through that list. And they can pick up whether you are in compliance or not in compliance. They do the exit interview with you so you have a general idea of where you stand. And then you get a formal written report. And then you have to address that report with a correction plan.

And then they also give you a time and they say, "We will be back in 45 days", depending upon the nature of the deficiency. It could be 30 days or 45, or it could be three months. And then they come back in. If those

deficiencies are still there, then, yes, you know, they shut down the nursing home; they, you know, withdraw your Medicare/Medicaid payments because you are not in compliance.

So certainly there are processes that are already out there that can be looked at that other regulatory agencies are using that the industries that have to comply with them feel are just as burdensome as this industry may feel about HAACP. But it's like, okay, it is here now; how do we do it.

And with the nursing home community, when they first brought in MDS and those plans, they sat down with them and did the orientation. And there was a start-up time. And then when they came back, it was -- they used those plans to see whether or not you were in compliance.

MS. SMITH DeWAAL: And, Donna, the time in which you can come into compliance though is limited --

MS. RICHARDSON: Right.

MS. SMITH DeWAAL: -- by -- to like 30 days, 45 days. And in this situation, depending on the nature of the violation, it might even be -- or the gaps --

MS. MUCKLOW: Deficiencies.

MS. SMITH DeWAAL: -- in the plan, it might even be shorter because there are other public health issues.

MS. RICHARDSON: You know, unless there are -- I

mean, unless you have a deficiency that is considered a life threatening -- you know, something that is just criminally grossly negligent, then, you know, you are given a period of time to correct that.

And if it is something that is life threatening or grossly negligent, then, no, you don't because it's like this is more than just sort of, you know, an omission or by mistake or whatever, you know. And so certainly, those -- you know, those kinds of deficiencies and violations can be dealt with.

But what you are looking for are the things that, okay, people didn't do because they didn't understand or they didn't do because they, you know, didn't have the trained help or whatever. But I think you can look at the processes like that, that HCFA uses and even OSHA uses and to look at those as a guide to the processes for HAACP.

MS. HALL: It is possible and probable that there is like a bell-shaped curve. There are people that are doing overkill on their programs and doing a lot more than they need to. And it is possible that people are doing under what they need to.

And I am sure both of them mean well. But they don't have the idea, you know, the idea. This is not just -- the concept of what they should be doing. So in this regard, this particular type of check is desperately

needed.

CHAIRMAN JAN: So the process then, at least from what I have been hearing, I think, first off, we need to have the second part of this technical committee meeting or this technical meeting.

And probably I think it would be a good idea to have either a separate or a part of it or a day before or a half a day before or after with some of these experts to go over this thing and make sure that this is the right tool, the right tool; are the right questions being asked from more or less a neutral perspective, just a strictly HAACP perspective. This would be the Dane Bernards, what is it, Robert Shaw?

MS. MUCKLOW: Savage.

CHAIRMAN JAN: You know, these people that are -- that the HAACP Alliance -- these folks that -- that that's -- they are the experts. They are recognized as experts because FSIS is a good idea, but I don't know that there are necessarily a lot of experts in HAACP and FSIS or certainly to have to rely on some of these. And it doesn't mean to exclude FSIS. I'm not saying exclude them.

MS. MUCKLOW: But FSIS has had people teaching HAACP. So their teachers should meet with them.

CHAIRMAN JAN: So that would be the -- I think the first step would be to make sure that this is the right

thing. And then I think --

MS. SMITH DeWAAL: But, excuse me, Lee. The HAACP Alliance -- I am more familiar with them in the seafood context than in the meat and poultry context.

MS. HALL: No, they are meat and poultry.

CHAIRMAN JAN: No, they have done all the training and they've got trainers and they've certified all the trainers for meat and poultry.

MS. SMITH DeWAAL: All right. It's a separate -- is it --

MS. MUCKLOW: Absolutely separate.

MS. SMITH DeWAAL: Okay. Thank you.

CHAIRMAN JAN: It used to be called the International HAACP Alliance.

MS. SMITH DeWAAL: Because I wasn't impressed with the seafood people, so --

CHAIRMAN JAN: No, in fact, this one had the -- didn't they have the Meat and Poultry HAACP Alliance? That's what it's called? Yes. It used to be International Meat and Poultry HAACP Alliance.

MS. MUCKLOW: It was called the International HAACP Alliance.

CHAIRMAN JAN: And then they changed it to --

MS. MUCKLOW: They dropped the words, "meat and poultry."

CHAIRMAN JAN: Oh, they dropped the "meat and poultry." I thought they dropped the "international." They kept the "international." Okay. But, yes, they've been -- and so -- and they are the ones that work with the Dane Bernards and those people that are known in the industry.

I think the next step -- I don't know that we ever said it, I think we kind of implied that -- would be education. I think there needs to be education of those people that are going to be reviewers by, you know, these -- again, these qualified people.

Number one, if the questions are there, how they interpret those questions. And it is nice to give this microbiological 1997 deal and have that in your mind. But having it in your mind by reading it and having it in your mind by going through a period of training -- and this would be a good time to make this available side-by-side with industry because they need to be able to use this for a tool themselves.

And, see, you understand what you are supposed to get out of that, not just say, "Well, I know it's in here." But know -- okay, "How am I supposed to interpret that?" So I think we need to have some kind of training or FSIS needs to have kind of training for those individuals that will be a part of the team, make it available to industry.

And then make that document available when there

is a selection, whatever method it is -- if they notify you that -- I mean, they pick your plant, then give you some notice, two weeks or whatever, to let you know that we are coming and these are the documents that we will be asking for. I'm not sure it wouldn't be bad to say have those ready.

We will look through the documents first. We will take them -- or put us -- either provide us an office or let us take them back to our hotel room and whatever. And we will look through the documents, come up with the questions, and then we will go do the hands-on because the first part is the document review anyway.

So why tie you up with questions. We will document questions and then we will spend an hour or two with you instead of a day or two with you on the documents.

MS. HALL: That's true.

CHAIRMAN JAN: That's just talking.

MR. ABADIR: Actually, for example, what is happening actually in this case is that when you go for any audit that you want to do even for your HAACP plan, you need to work on the documents first. So from the audits that, for example, I have from companies outside that come over to audit -- which we have a company from Europe that comes and audits every three months.

They spend the first day just in documents. So

you give them all the records. You spend one day looking at the records. And then the next day, then you meet with them so they have an idea and they talk to you. After they look at the flow charts and see the processes, they can analyze which areas are sensitive, which hazards are to be controlled.

One of the important things that I see here which is a different point than what I am talking about here and I wanted to raise is this document does not have any markings. So which is acceptable? If I am failing in three or four areas here, then that means the HAACP is bad or what?

There is no level of -- in each step of this, there must be a five-step or a three-step marking, "Acceptable, Not acceptable," whatever, "Good, Fair, Excellent." There should be in every stage of this an acceptable and there is a mark at the end that is added up to see if the system is running throughout those areas that are critical.

And the questions of being critical or CCPs should be on a separate -- like two phases, A and B. If you fail anything in A which you are talking about CCPs, then there is no need to go further in the process.

MS. MUCKLOW: Well, I'm all for it. But when they sit down and work this through with the industry experts that they can refine this document and put it together in

final form because it is a regulatory document and a regulatory document that is going to be the basis for possibly enforcement action. We all hope not, but a document that is going to be the basis needs to be a completed document.

CHAIRMAN JAN: Well, then, yes, I would agree that we ought to have some system of setting this --

MS. SMITH DeWAAL: What the anticipated answers are, and then you can still have room to write in. But --

MR. ABADIR: I mean, FDA has a document like that right now when they come for a complete audit and they go with markings everywhere. They have the questions like this and they are on a separate document that is attached, and they go by question and see how they review.

And they will show you the review, "This is where you stand overall." And if there are no major things or CCPs, then they will let you have 35 days or 45 or even 90 days to come back to the same issue and discuss it. For example, addressing a boxing or addressing a hazard that is there that was not there before.

MS. SMITH DeWAAL: But -- and I think your point is a good one. If you -- if they are missing a specific hazard, then everything else throughout the document is going to be inadequate because that one hazard is missing.

MS. RIGGINS: Is FDA using its Form 483 to

document the deficiencies? So they are still using 483s to --

MR. ABADIR: That's correct.

MS. RIGGINS: Okay. I just didn't know if they had created a new document. Okay.

CHAIRMAN JAN: So then the next process, if we would just kind of sketch out a process, then after the plant is notified, the reviewers look at the documents and they spend an appropriate amount of time doing the review and have an exit conference to be able to brief based on what they found, give you a preliminary review -- preliminary report to be followed by a written report.

And before that written report is filed in any kind of position to be a completed document, it would allow a period of time for the plant to have responded to those with -- if they have any legitimate responses, to say -- to counter some of the findings, to say what they are going to do to make the corrections or what they have done or whatever, so we can have a closed document. And once it is a closed document, then it becomes available for public records.

MS. MUCKLOW: And it becomes an actionable document at that point.

CHAIRMAN JAN: Right.

MS. MUCKLOW: I mean, that's the way audits work

with CPAs and so on.

CHAIRMAN JAN: It makes sense to me.

MS. MUCKLOW: Or a management review. I mean, this needs to be modeled after the way audit reports are managed.

AUDIENCE MEMBER: Could you capture that thought again for me, please, the process? I couldn't get it down.

CHAIRMAN JAN: Okay. Starting from the beginning?

AUDIENCE MEMBER: You started with informing them or --

CHAIRMAN JAN: Yes, naturally, you give them a notice of the date. And that can be -- the notice of date. And then the next thing would be when the date arrives, then the plant will have the records together. Okay. The third step would be the reviewers review the records without the plant manager. And the next step would be interview with the plant. And the fifth would be system review.

MS. MUCKLOW: You are good, Lee.

MS. SMITH DeWAAL: You should do this for a living.

CHAIRMAN JAN: And on (4), interview with the plant regarding finding of step three maybe, because that's what that part is for, just to get all those issues resolved. Okay. So then system review. Then (6) would be an exit conference providing a preliminary report.

MS. MUCKLOW: You're just writing his report for him tomorrow, is that it?

CHAIRMAN JAN: Yes. Okay. Number (7) would be a period of time --

MS. HALL: Follow-up letter.

CHAIRMAN JAN: Oh, wait a minute. That's right. I'm a step off.

AUDIENCE MEMBER: Okay.

CHAIRMAN JAN: This would be formal report, written formal report to plant.

MS. SMITH DeWAAL: And that should have a set time for full compliance?

CHAIRMAN JAN: Yes.

MS. SMITH DeWAAL: Okay.

CHAIRMAN JAN: We will need a -- we will want to specify a time from the exit conference to when the formal report needs to be written. And I would say two weeks would be --

AUDIENCE MEMBER: Two weeks from here to here, for a specifying time?

CHAIRMAN JAN: Right. Two weeks between (6) and (7).

MS. MUCKLOW: How about a report to clients --

MS. SMITH DeWAAL: What about fixing the problem?

MS. MUCKLOW: -- with the specific requirements

within two weeks?

CHAIRMAN JAN: That would be the next, requirements.

MS. MUCKLOW: No, not there.

AUDIENCE MEMBER: Not here?

CHAIRMAN JAN: No, I think what we need to do -- we need to give FSIS reviewers a chance to get back and write a formal report. So give them two weeks.

MS. MUCKLOW: Formal written report to client with specific requirements within two weeks.

CHAIRMAN JAN: Right, there you go. Right there.

MS. HALL: Requirements and compliance dates.

CHAIRMAN JAN: Okay. Now, the next step would be a period of time -- and maybe 30 days just as a -- and that can be determined, but a period of time and maybe 30 days as an example, for plant response.

MS. SMITH DeWAAL: When are they incompliant?

CHAIRMAN JAN: Well, hopefully they are in compliance. They are responding to minor things. Now, then again, that was --

MS. SMITH DeWAAL: I mean --

MS. RIGGINS: Well, I guess what I would say is that if in the course of the review FSIS were to find that there is something that truly is a system failure --

MS. SMITH DeWAAL: Failure.

MS. RIGGINS: -- then 417.3 would kick in.
CHAIRMAN JAN: That would come into play, right.
MS. RIGGINS: And they would then have to, you know, go into corrective action.
CHAIRMAN JAN: Let's put that in.
MS. MUCKLOW: 6(a).
CHAIRMAN JAN: 6(a) would be --
AUDIENCE MEMBER: Okay. Could you --
CHAIRMAN JAN: Any 417 failures -- wouldn't that be a good way to put it?
MS. RIGGINS: Yes, any failure --
CHAIRMAN JAN: Or any HAACP --
MS. RIGGINS: -- or HAACP failure that was --
MS. MUCKLOW: Any 417 failures.
MS. SMITH DeWAAL: That's not English. I mean, people in the meat industry --
MS. MUCKLOW: It is industry.
MS. SMITH DeWAAL: No.
MS. RIGGINS: Any conditions that --
MS. SMITH DeWAAL: Any HAACP failure --
MS. RIGGINS: Well, any --
MS. SMITH DeWAAL: -- to make it understandable to the public.
MS. RIGGINS: Okay, any HAACP failure.
MS. SMITH DeWAAL: Thank you. Most of the public

understands HAACP better than 417.

MS. RIGGINS: Okay.

MS. SMITH DeWAAL: But at least the people --

AUDIENCE MEMBER: Any HAACP failures, 417 --

MS. SMITH DeWAAL: Any HAACP failures --

CHAIRMAN JAN: Would result in appropriate regulatory action immediately.

MS. MUCKLOW: I mean, Agency always has that option.

CHAIRMAN JAN: Yes. That goes without saying.

MS. SMITH DeWAAL: Well, then let's just articulate it.

MS. RICHARDSON: Well, one of the things that I think also we would have to be definitive about is that the process doesn't work if there is no integrity in the -- within the system. That if, in fact, you find systems failures, that people know it and they correct it or they get their hand spanked. If people know that they are not going to get their hand spanked, then they don't do what needs to be done.

So that in order for the system to work in a cooperative measure is you have to know that if you don't comply, that indeed, you know, you are going to suffer the consequences. And part of the problem is the inconsistency in the application of agency action. And so what you have

to do is to make sure that agency action is consistent.

MS. SMITH DeWAAL: One thing as we are doing this, one of my concerns it that you are saying -- I mean, you are essentially giving two weeks for the Agency to write their report and 30 days. And when we are talking about restaurant inspections, when there is a violation, they have to correct it either within 24 hours, sometimes they are closed down immediately.

I mean, I know you think that is covered under 417. But I think we need to be clear that any systems failure that -- should be cleaned up much more rapidly than six weeks.

MS. MUCKLOW: Yes, but the problem -- this is a review team process. This is not your standard inspection oversight.

MS. SMITH DeWAAL: Can we say appropriate and immediate regulatory action? I mean, that would make me more comfortable.

CHAIRMAN JAN: Immediate?

MS. SMITH DeWAAL: Or immediate regulatory action.

CHAIRMAN JAN: Appropriate immediate.

MS. RICHARDSON: I think we also said that depending upon the deficiency, then that also, you know, determines the kind of response that's needed. Granted you have an exit interview in which you say, "Look, these are

the things that we saw that were wrong. These are the things that need to be corrected right away." Okay.

Then you send a written report. And the written report is just a confirmation of what you've gone over with them and you have given them their checklist. And they know this has to be done.

When they get the written report back, then they have an opportunity to respond and say, "Yes, these were the things that were found and this is what we have done to date." And they know that in 45 days, the Agency comes back and --

MS. SMITH DeWAAL: Yes.

MS. RICHARDSON: -- and if they haven't done it --

MS. SMITH DeWAAL: And that's not up here. We don't have rechecking. Can we do a number (9)?

CHAIRMAN JAN: A recheck.

MS. SMITH DeWAAL: Yes.

MS. RICHARDSON: So the plant has responded --

CHAIRMAN JAN: For a follow-up?

MS. SMITH DeWAAL: Yes.

CHAIRMAN JAN: I would say that rather than the review team coming back, that the district managers --

MS. SMITH DeWAAL: Okay.

CHAIRMAN JAN: -- be responsible or be a delegate of the review team to follow up to verify this is taken care

of.

MS. SMITH DeWAAL: That's fine. So number (9) would be the district manager.

CHAIRMAN JAN: Yes.

MS. SMITH DeWAAL: Although would you be certain you would be getting uniform applications then across all the districts or would some districts -- I don't know.

CHAIRMAN JAN: Well, it's either that or --

MS. SMITH DeWAAL: I mean, the review team would be more consistent.

MS. RIGGINS: Well, we would have to have our district managers either on phone conferences or on a regular basis to make sure that we were applying it consistently across all district areas. I mean, that's our job, to make sure that we have consistent application of the standards.

MS. SMITH DeWAAL: But the review committee would know instantly whether what they have seen --

MS. RIGGINS: Well, it's going to be --

MS. SMITH DeWAAL: -- was addressed or not.

MS. RIGGINS: Basically, what we thought is about five teams of four to five people a piece. So it is going to be a finite number of people who are going to be doing these reviews who will see plants over and over and over again. And they will begin to build an experience base

because, you know, they will learn from each review.

So we are not going to have a lot of different people all doing this. There will be a finite number of people who will have that role. And inherent in that hopefully is the consistency.

I mean, if we have -- and they will be talking to each other. There will be -- I hate to use that word -- correlations, you know, among the teams. So that we are sure that we are getting the same application of the principles across the Agency.

CHAIRMAN JAN: That's another critical reason I think that we don't want that review team to go back and have to do the review, because there is, what, 5,000 plants that need to be looked at or 3,000 or whatever it is. And if you only have five teams, they need to make the initial finding and then redirect the district manager -- that district manager then needs to follow up to make sure that -- and that wouldn't be in every case.

The district manager wouldn't have to come in in every case because I am hoping there will be some of these that had no major -- or anything. They may have, "Well, maybe you should have used 'is', and you used, 'was'," or, you know, some little small things they may want to comment on that really have no real great effect.

But if you have something that you just completely

ignored this significant hazard and it's reasonably likely to occur, then, yes, we need somebody to follow up on that and do that in an appropriate length of time. And if it is a failure, then we withhold -- just like you would if our inspector found a failure or was able to do it. We put the withhold on it until whatever action is taken.

MS. RIGGINS: Well, if something rises to the level of an NR --

CHAIRMAN JAN: Right.

MS. RIGGINS: -- you know, as we said, 417.3 is going to then prevail and you will have to write a corrective action plan for that particular instance, whatever that situation is. And the district manager would be responsible for following through on that. I mean, that is the way things work now. And that wouldn't change in this situation. This isn't going to be set apart and outside of the core enforcement or core regulatory responsibility that we have.

CHAIRMAN JAN: Now, the inspectors are going to continue -- they are going to do the basic compliance and then they are going to do the other compliance on a daily basis. And this will be a good tool once it is the right questions and the right training for the circuit supervisors, the district managers to use when they do their own reviews, way ahead of when they are going to be called

just so they will be ready.

This will be a good tool for the plants to use to say, one of these days I might be picked. And not only for that reason, but hopefully this tool will be the right people -- and I think it's a good start. I think there is a lot of good stuff in here.

But, you know, get the people and make the training available to industry, those that are interested, so they know how they are supposed to interpret what the '97 document intends or how -- you know, what we want them to gain from that, how to apply that. Then I think that the industry can be steps ahead.

And when the review team comes, most of the industry will be -- all they have to do is pull out their drawer or whatever and go on, and not really be stressed out by it. Because the idea, again, I think is not to be got-you. It's a cooperative -- and we need this out long before. Let it be a tool for everybody.

MS. MUCKLOW: Lee, would you do me a very great personal favor? You don't need to write this up on the board. You can remember this one. Don't liken this to the Lawrence review process.

CHAIRMAN JAN: You don't like that?

MS. MUCKLOW: Well, it will fall on the landing pad in the wrong way. It will send the wrong message. This

is a cooperative effort. There was nothing cooperative about the Lawrence, Kansas comps.

MS. RICHARDSON: They may feel that way about the reference to OSHA.

CHAIRMAN JAN: Yes, that's not a good one either.

MS. RICHARDSON: Lee, you could say, you know, the HCFA -- HCFA compliance and then --

MS. MUCKLOW: We don't know what HCFA is.

MS. RICHARDSON: Health Care Financing Administration.

AUDIENCE MEMBER: Do you want something else included?

MS. RICHARDSON: Yes. Don't use OSHA. Yes.

MS. MUCKLOW: Take OSHA out. Let's call it HCFA.

MS. RICHARDSON: Yes.

CHAIRMAN JAN: The nursing homes and other agencies -- other regulatory agencies.

MS. MUCKLOW: HCFA.

MS. RICHARDSON: Yes, HCFA. HCFA or --

CHAIRMAN JAN: Is that heating and air conditioning?

MS. SMITH DeWAAL: Are we done? Can we go home?

CHAIRMAN JAN: Well, does anybody else have any --

MS. MUCKLOW: I think we're done.

CHAIRMAN JAN: -- anybody out there interested in

anything? Okay.

MS. MUCKLOW: We've got the experts from Down Under out there.

CHAIRMAN JAN: Well, that's -- I think we covered it pretty well. And when I saw this, I didn't know what we were going to talk about. But we found something, didn't we?

MS. MUCKLOW: Yes.

AUDIENCE MEMBER: Has everybody had a chance to look at what was written that they said to see if it was accurately correct?

(Whereupon, at 8:09 p.m., the hearing in the above-entitled matter was concluded.)

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National Advisory Committee on Meat and Poultry Inspection/HAACP System In-depth Verification Review/ Resource Allocation Standing Sub-committee
Name of Hearing or Event

None
Docket No.

Arlington, Virginia
Place of Hearing

November 3, 1999
Date of Hearing

We, the undersigned, do hereby certify that the foregoing pages, numbers 1 through 47, inclusive, constitute the true, accurate and complete transcript prepared from the tapes and notes prepared and reported by Gabriel Thomas, who was in attendance at the above identified hearing, in accordance with the applicable provisions of the current USDA contract, and have verified the accuracy of the transcript (1) by preparing the typewritten transcript from the reporting or recording accomplished at the hearing and (2) by comparing the final proofed typewritten transcript against the recording tapes and/or notes accomplished at the hearing.

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