UNITED STATES
DEPARTMENT OF AGRICULTURE

NATIONAL ADVISORY COMMITTEE ON)
MEAT AND POULTRY INSPECTION)
STANDING SUBCOMMITTEE NUMBER 2)
INDUSTRY'S PETITION FOR)
PROPOSED CHANGES TO HACCP)
FINAL RULE --)
AGENCY CURRENT THINKING)

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Saturn Room
Holiday Inn Capitol
at the Smithsonian
550 C Street, S.W.
Washington, D.C. 20005

Tuesday,
June 5, 2001

APPEARANCES:

MICHAEL MAMMINGA, IOWA DEPARTMENT OF AGRICULTURE
GLADYS BAYSE, DEPARTMENT OF CHEMISTRY, SPELMAN COLLEGE, GEORGIA
CAROL TUCKER FOREMAN, FOOD POLICY INSTITUTE, CONSUMER FEDERATION OF AMERICA
CHARLES LINK, ROCCO, INC., VIRGINIA
JOHN NEAL, COURSEYS SMOKED MEATS, ARKANSAS
ELSA MURANO, DEPARTMENT OF ANIMAL SCIENCE, TEXAS A&M UNIVERSITY
LLOYD R. HONTZ, NATIONAL FOOD PROCESSORS ASSOCIATION
JOE HARRIS, SOUTHWEST MEAT ASSOCIATION
DR. JOSEPH L. BLAIR, HACCP CONSULTING GROUP, LLC
MARK D. DOPP, AMERICAN MEAT INSTITUTE
PAT STOLFA

P R O C E E D I N G S (7:05 p.m.)

MR. MAMMINGA: Well, I'm familiar with some of us on the committee, but less familiar with others. And Gladys Bayse from the Department of Chemistry and Spelman College in Georgia to my left sits next to me in our committee meeting.

Gladys, we're going to be talking about HACCP tonight. We're going to be talking about prerequisite programs to HACCP. And I know what it's like to either think I know something or know I don't know something. So where do you fit into HACCP as far as your area of expertise?

MS. BAYSE: Well, that's a good question. I thought you were going to ask me to define it. So I had my encryption here.

MR. MAMMINGA: Oh, no.

MS. BAYSE: The acronyms are tough, I guess, for academics. I'm a biochemist by training, although I'm in a chemistry department. And I do some research in the toxicology area. We look at feed additives, specifically. Arsenillic (phonetic) and acid in rocks are some which are used in slime and in poultry feed. So that's more of a sort of FDA thing, I guess. But it has led us, of course, into some literature searches and the like.

I have some familiarity with the kinds of things

we talked about today, which are really microbiological and biological. I have less experience, actually, working with those.

MR. MAMMINGA: Okay. Very excellent. John Neal, obviously, from Courseys Smoked Meats in St. Joe, Arkansas, operator of a federally inspected establishment.

MR. NEAL: Yes.

MR. MAMMINGA: John, why don't you share with us your involvement with HACCP, being you're a federally inspected plant?

MR. NEAL: Well, we developed our HACCP program two years ago. We've been USDA-inspected for 27 years. And we've seen them come and go. Our plant has met all the criteria through the years.

I got the early warning and decided -- I went ahead and, even though big industry did it, I went ahead and started going to -- attending schools and went ahead and got certified and developed my program. So when it came in, we only had some minor changes.

We ship hams nationwide, cure and smoke meat, hickory smoke it, and we ship it coast to coast. It's a big part of our business, plus, you know, we average a lot of people per day in our store, even though it's a small, family-owned retail outlet. And we're very aware of SOP's sanitation and the HACCP program, in general. And all our

employees are.

We have approximately 10 employees. I made them all HACCP-compliant, so they understood what we were doing, even though only about three of them have to deal with the -- some of the -- about two of them are dealing with the paperwork, besides myself. And --

MS. FOREMAN: What's your production?

MR. NEAL: Production?

MS. FOREMAN: Yeah.

MR. NEAL: Pork.

MS. FOREMAN: Just hams or --

MR. NEAL: No, just ham and bacon.

MS. FOREMAN: Ham and bacon. And what's your poundage?

MR. NEAL: Poundage?

MS. FOREMAN: Well what's, you know, what's your size business? How much, in general?

MR. NEAL: Oh, I probably do about, in hams, I probably do about 400,000 pounds a year in just hams.

MS. FOREMAN: With 10 employees?

MR. NEAL: Yes. And bacon, it even goes, for this lab I'll process, between Thanksgiving and Christmas, I'll do 1,600 slabs of bacon alone.

MR. MAMMINGA: A popular product.

MR. NEAL: Yes. Our bacon is very --

MS. FOREMAN: You live in the --

MR. NEAL: We've been there a long time. And we've been in business for 60 years.

MR. MAMMINGA: John Neal, I just got done with you. Charles Link, Rocco, Inc., Virginia, you're a HIMP plant?

MR. LINK: We have a HIMP plant.

MR. MAMMINGA: You have a HIMP plant. I didn't mean you personally, Charles. Okay. You have a HIMP plant. And why don't you share with us your involvement with HACCP.

MR. LINK: Well, we've got three processing plants, one turkey slaughter, one chicken slaughter, which happens to be a HIMP plant, and we've got a -- processing facility. Excuse me. Carol, don't ask me the pounds, because I can't tell you. I can tell you about how many birds we slaughter a day if that'll help.

MS. FOREMAN: Okay.

MR. LINK: And it's, on the turkey side, it's around 85,000 a day; chickens, it's around 280,000 a day. So that's a lot of pounds. We had two of our plants are large plants. So we've been in the HACCP now for, what, three years, I guess. And then the other is -- falls into the middle category. So we've been there two years.

We had a plant in North Carolina that we had to

bring up at the same time, but we've since closed and sold that place. So my involvement, my position is directly regulatory affairs. So I work with the QC people, the production people to make sure that everything's happening, and we're staying in compliance with the regulations as they're coming out.

I've been involved with HACCP since way, way back. I think I was in Atlanta in the first meetings when we were talking about it way back in the early '90s, '91, '92, somewhere in there. We've been going to different HACCP training classes ever since. So I've been involved since way back.

MR. MAMMINGA: I think everyone knows Carol Foreman and certainly has been involved in FSIS ever since the '70s. And I am bureau chief of a state program. We have about 200 plants under inspection.

Oh, about a hundred -- a little over a hundred of them are inspected plants. Seventy of them may be slaughter under inspection. The other 30 process under inspection. And then we have somewhere around a hundred exempt plants -- custom, red meat, and poultry. So, you know, HACCP we've been kind of involved with it since it was -- since it started.

I have a thought today. I sit and listened to everyone talk. And I didn't say anything. And I would like

-- we have a lot of people here that know a lot more about this than I do. But one of the things, I made a couple of lists of acronyms up here.

And one of the things, frankly, when I listened to Carol talk and when I listened to industry talk, when I went to HACCP school and I went to industry HACCP school before I went to regulatory HACCP school, and then I got involved in helping organize the Iowa and the small federal plants in Iowa to go, one of the things that's always confusing is GMP's, their Good Manufacturing Practices, SOP's, Standard Operating Procedures, they are the prerequisites of HACCP.

If you're going to do HACCP with no government, with none of us regulators around, this is where you're going to work your way through. Would everyone agree with that? Isn't that so?

Now, when the government stepped in, my friends at FSIS and myself, we came up with SOP's and generic biotype I E.coli testing in the slaughter plants as the prerequisites to HACCP from a regulatory standpoint. And then we went into HACCP.

It's a little different when you talk about the criticism that may be leveled at the agency or through them to my program from folks who are interested in food safety or the watch dogs, like TAO and OIT. They are looking at how those of us in regulation and regulatory work, they are

looking at how we do this right here. Isn't that correct?

So when we talk about HACCP it wasn't, you know, the FSIS didn't develop it. I didn't develop it. It was just a process to develop -- so when we look at the industry petition, I think -- and this is the only thought I'm going to put in your mind -- the industry, if they are trained and know what they are talking about, have been taught that these are general. This is very general. The good manufacturing practices are a very general concept.

This is a little more specific, but this is the sanitation standard operating procedure is very specific, pretty often operational. HACCP plans are very specific. And these are food safety. And these can affect food safety. But they are not necessary specific enough. Go ahead, Carol.

MS. FOREMAN: I just was going to ask where you were going to put the salmonella testing.

MR. MAMMINGA: I'd forgotten it. I keep thinking there was two things that I had to do. And so I forget the third one. This is one we had to do, and these through here are the industry; that is, in the prerequisite program safety. But somewhere in here and how they can affect that, this is the wiggled spot that you're talking about.

Can these, in any way, in combination with everything else affect this? Is that so? Okay. I'd just

like to try to keep what we were all taught in industry school separate from what we, as regulators, do. Okay?

MR. LINK: That's not so easy to do.

MR. MAMMINGA: What's that?

MR. LINK: Keep these things separate.

MR. MAMMINGA: Oh, it's terrible.

MR. LINK: The thing that, you know, when you think about GNP's, SOP's, prerequisite programs, things that have been done for years and years to ensure that the employees wear hair nets, if nothing else, to keep hair out of food, thermometer calibration, there's tons and tons of things that we do, the government followed into sanitation and don't really follow into HACCP, as I understand in HACCP in terms of trying to identify critical points in the process that can make or break product safety.

But when you look at prerequisite programs and think how they might impact HACCP, when you go through hazard analysis and you try to figure out what's going on in this process and what is the risk of anything going wrong, well, Pat's always telling, well, in the absence of controls. Well, but we've got controls.

So when you've got controls then, and you know they are there, it impacts your thinking in terms of hazard analysis, which ultimately can impact your thinking in terms of is there a CCP or not.

MR. MAMMINGA: Hold that thought for just a second, would you?

MR. LINK: Yes.

MR. MAMMINGA: Elsa Murano?

MS. MURANO: That's very good.

MR. MAMMINGA: Department of Animal Science, Texas A&M University. Elsa, we kind of went around the table just before you got here and mentioned to everyone what our involvement had been in HACCP or how comfortable we were with it or what we knew about it before we entered this long discussion tonight. Would you like to share with us?

MS. MURANO: Sure. Well, I've been involved with HACCP in the sense of training, doing a lot of training of industry and having a lot of workshop teaching experience. I have been acquitted to by the International HACCP Alliance as an instructor, HACCP instructor. So I've taught HACCP courses not only here in the U.S., but also in other countries, in Argentina, Mexico, Honduras, some for the World Health Organization.

And in addition to HACCP, of meat and poultry as far as being applied to that, I've taught some workshops as HACCP replies to other kinds of products, nonmeat, nonpoultry. Since about 1992, I've been doing that.

MR. MAMMINGA: Very excellent. Well, she could teach school for us. That's very excellent.

MS. MURANO: I recognize the books.

MR. MAMMINGA: Well, I brought this along with me all the way from Des Moines, because I knew that somewhere in this process when I saw what we were going to discuss tonight, we might need some technical assistance. And I didn't know, you know -- I do not consider myself an expert, although I've gone to the HACCP training five times.

I went with all the Iowa plants and all my staff. And I'll tell you, you know, Dr. Joe Cordray, who teaches it in Iowa, told us at the very beginning we would have to be exposed to it at least seven times before we could think that we might even have some clear idea of how it went.

And I found that five has got me feeling a little dangerous. But I don't think I want to write up any plans for anybody. And that is a very important, I think, if I have any good points, is to recognize that -- what I don't know. And there are other people smarter than me in this.

MS. MURANO: Well, there are people who are way smarter than me in this, who have written that book, for instance, say that every time -- and it's very true -- every time we teach our workshop, you learn even more. So I don't think you ever can sit down and rest and say I know everything there is to know about HACCP.

MR. MAMMINGA: When we look at the issues before us tonight, the three things that FSIS has asked us to do

with prerequisite programs, this has a whole chapter about prerequisite programs and says simply it is the appropriate term to describe a range of programs that are necessary to set the stage for HACCP-based systems. Okay.

Now, industry has come to the government with a petition and said, well, we would like you to reconsider part of your regulations. So now I think -- again, you tell me if I'm wrong -- but I think we have -- we are stepping out of this arena, a whole package of things that comes up to a single concept of process control.

And now, we're looking into the regulations. And as Carol and others pointed out to us today, there are some that feel that our activity as regulators in this are not appropriate or thorough enough or cover enough or cover the right things. And on the other hand, we have industry that's saying, well, we'd like for you to consider some of these things. So that's, I guess, the point that I would start. I am open for how you want address this.

Next, I have my tab seven open in my book where there are three questions that are put to us. And I do not know if you want to regurgitate that two pages of agency issue paper on this petition. Should we do that to refreshen ourselves? Or do you all feel comfortable enough for that to go directly to the three questions that they have put to us?

MR. NEAL: Well, let me say something just about what you said at the last -- and, I think, Carol kind of disagrees with this -- but at the same time is what was presented to us when we started HACCP and tell me if it goes that far back to '92 and, Carol, you tell me here. But they say that what it was going to is to be basically self-regulated with supervision. And you have a verification record-keeping procedure.

That basically was the bottom-line procedure for why HACCP was developed is to slowly integrate us and to make us more efficient. I, personally, think talking to a lot of the bigger industries in Arkansas -- I've talked with Charles and other people that -- and people from different organizations, that generally industry likes HACCP. I enjoy HACCP in our plant.

I think we're more aware, my employees are more aware, even in a small plant of what we need to do. We see little things that we didn't see before. Usually, nothing that was identified as prerequisite, we did it every once in awhile. But it's nothing that affects your sanitation. So we're pleased when we see things that don't really even affect us.

If it's a spot dirty in a corner by the cookbooks in the retail area, we see it. We're more aware. And down the road, this is what the plan -- this is what we were led

to believe -- is this not right, Charles -- that we were basically regulating ourselves with occasional supervision and verification by the USDA and FSIS. So that's all I wanted to say. Okay.

MS. FOREMAN: Actually, that's really very helpful, because I think we're going to see a pretty good size of the problem here. I think you're absolutely right. That's how HACCP has been defined when it is used as a private program, when it's used by a company to assure that the company is going to make a level of quality and safety that the company desires. And when it was proposed in that way, we opposed it vigorously.

MR. NEAL: Did you?

MS. FOREMAN: We did. And on the grounds that the USDA is assigned to regulate product and to not let it leave the plant without assuring that it is safe and in that way, of course, it is very different from FDA, which does not have that requirement on it as a matter of law.

But meat and poultry are the only products sold to the American consumer that come with a stamp of guarantee by the United States Government. God, if I could get one on my car, I would sure have it. So it's something very special.

And we pretty much argued to the government that -- I don't mean pretty much. We very vigorously argued that if you want to adapt HACCP so that it can be used as part of

a public health regulatory program, it had to have some things added to it, for example, specific verification steps that could show that it was meeting a public health goal.

Now, we all put HACCP into place without changing the law. And we all have to live with that. You know, some of these days we'll probably change it. And given that change, the consumer organizations that work on these issues strongly supported HACCP. And we have continued to.

The Office of Inspector General last summer put out a report saying that the FSIS has reduced its oversight short of what is prudent and necessary for protection of the consumer.

MR. NEAL: Who said this?

MS. FOREMAN: The Office of Inspector General of the USDA after doing an extensive audit of the operation of the program. And I think what the agency's trying to do now, and so we all come to this, you know, like the elephant which we got a different hand on it, but we could only support this concept if it had some performance standards that say you're getting there. And we're troubled, of course, by the inspector general's suggestion that USDA has --

MS. MURANO: I wish we had that. I mean, that should have been in our materials.

MR. NEAL: Right.

MS. FOREMAN: It's just that --

MS. MURANO: Well, I figured --

MS. FOREMAN: Did anybody bring it? Did anybody bring it? It's --

MS. MURANO: Because you do have that. You should read that.

MS. FOREMAN: There are some of us who spent the six months -- oh, gosh, it's been a year now, hadn't it, Pat?

MS. STOLFA: Yes.

MR. NEAL: What's the regulation? What was the -- is there a date on that?

MS. FOREMAN: June --

MS. MURANO: June, last year.

MS. FOREMAN: -- 2000. Yes.

MR. NEAL: June 2000.

MS. FOREMAN: And --

MR. NEAL: Do you see?

MS. FOREMAN: It's in your packet.

MR. MAMMINGA: I'm sorry, John.

MS. FOREMAN: And GAO has also been critical, but OIG was especially critical. I don't agree with all their criticisms. But that doesn't make much difference.

MR. NEAL: Well, that's true.

MS. FOREMAN: So I think that USDA started this

response. Did the petition come just before the OIG report?

MS. STOLFA: About six months before.

MS. FOREMAN: That long before. Okay. So that's the context in which FSIS is trying to respond. Any time you change a government program that has 7,600 employees and covers 6,000 plants and you change it radically, you're going to have a lot of dislocation.

I think OIG could have acknowledged that a little more than they did. And I'm prepared, having said that, to go at the questions here. And I've got some additional questions and some suggestions, so however you want to proceed.

MR. NEAL: I'd like you to pick up on your general remarks. I didn't mean to cut you off, but I wanted to introduce --

MS. FOREMAN: I'm sorry. I cut in before you --

MR. NEAL: So, you know, I think here again it's a real good concept, because every plant that's in our program that I've ever dealt with in HACCP, they get to a point after implementation where they see the good things that have come their way.

I've never had a plant, believe it or not, those little old, cranky mom-and-pop operators that I've got, I've never had one of them look me in the eye and say that HACCP was a bad thing. They might complain about this or that,

but they'll say, you know, we're cleaner. We know what we're doing better. And that's right where you were in when I asked you.

MR. LINK: It forces you to walk through your process a step and see what you're doing and ask the questions. The part that we missed, I think, and the reason we submitted a petition was the part you put there that the guy left out of this, the prerequisite programs, because those things are integral to having a clean, safe plant.

They impact your thinking, obviously, when you're thinking about through your hazard analysis is it critical or not. Well, it depends on what I'm doing and what I've got going on. If you completely take them out of the picture and say, well, in the absence of controls and CCP that we can just outline with a program, I may not have.

So there was a question earlier about, well, is this thing going to take place at CCP. And, who knows, I mean, until you go through the process? Part of what, to your point, Carol, and maybe to the OIG, if you think about what they were looking at, we're looking at a food safety program, focus very much on food safety.

Prerequisite programs impact food safety, but they also impact other things, product quality. There's a lot of things that are out that once upon a time pre-HACCP, USDA was involved in. And they watched what they did. And we

had TCQ programs, and it was all in there.

MS. FOREMAN: Well, yes. That was my fault.

MS. MURANO: We thank you for it.

MR. LINK: It's actually a good program. But so when you think about it, we've taken all these things we've used and focused very much on food safety. So there's a lot of things that the USDA doesn't look at anymore. We still do them. They don't look at them.

MR. MAMMINGA: Well, then pre-HACCP, I think you'll agree that back in about '94 or '95 when we were waiting for a final rule, all the trade journals and all our government types were talking about what are we going to make them or what are they going to make us do? And that was paramount, what do we have to do? What am I going to have to do in my program to survive this shift?

And then the industry, they wanted to know one thing: What do I have to do, not what should I do, because HACCP is what should I do. And it is a whole system. The government -- Carol and I talk all the time -- the government does what it has to do or what it's --

MS. FOREMAN: What it really says is the government's going to do what it's going to do.

MR. MAMMINGA: And it will. It will. The thing of it is is that if you want to blend this into something that is proper and that everyone can live with, and that's

the trick that we've been handed tonight.

MS. FOREMAN: And if I could add one more thing to that, nobody serves on the Meat and Poultry Inspection Advisory Committee who runs a bottled dwelling plant, you know. I've never been in a dirty plant. And I'm sure, you know, if it was dirty the day before, it sure wasn't -- and obviously, all of the hooks and weights in this are put on there for the people who, in the absence of those, would not operate at an acceptable level, wouldn't run a --

MR. MAMMINGA: No.

MS. FOREMAN: So that's -- you know, I thought for many years that what the thing that the system lacked most was an incentive system to perform at a level substantially higher. If the crummiest guy in the country gets to keep -- have the seal, what's the incentive? So that's --

MR. NEAL: It's iniquity, test my loyalty.

MS. FOREMAN: I think that it has been an increasingly important factor in this.

MR. MAMMINGA: Carol, I appreciate your thought on that. You know, what is the incentive to excel? And yet, amongst the very groups that are working with this, there is a common thread of not wanting to be left on the outside. You know, so there's always a resistance to some system that allows a -- John does a great job in his plant. He ought to get this because of that. And that would be a tough sell.

MS. FOREMAN: I'll give you a gold star for that.

MR. NEAL: That helps. It's always --

MR. MAMMINGA: All right. We have three questions before us. And listening to your discussion today, I'd kind of like to beat over the head a part of what was proposed and the FSIS response to it.

Some of the most spirited discussion had to do with, specifically, if the agency believes it can develop a proposed regulation that recognized successful prerequisite programs in certain circumstances, it goes on to say the programs might have an effect on an establishment's hazard analysis or HACCP system.

And we bounced off the word that it might eliminate the need for a CCP. That seemed to be the most contentious issue. So we might as well face up to it. And let's talk it out first. I think we can address the others.

MS. FOREMAN: Could I ask something more basic, because before we met this evening, I went back and looked through the paper. I've got on page four here what prerequisite programs aren't.

MR. MAMMINGA: Page four of what?

MS. FOREMAN: Of their -- of the --

MR. MAMMINGA: Of the implementation?

MS. FOREMAN: Of the draft. No. I'm sorry. The draft that Pat passed out, "Current Thinking."

MR. NEAL: Page four?

MS. FOREMAN: Yes. It's a double-spaced thing. It's dated 5/17. Pat, have you all got a working definition of what prerequisite programs are in the context of HACCP and in the context of the Pathogen reduction in HACCP rule? I know you've got to write a new part. But --

MS. STOLFA: No. We don't have that, no. Basically, we took our direction from the recent literature that we reviewed. And the two documents which had the most substance were the microcommittee's '97 document, and there's a paper in the last several years by Sperber and others that was as good as anything that we came across.

MS. FOREMAN: So part of my problem is I don't know how you'll define it in the context of a new section 415.

MR. MAMMINGA: You mean how to define prerequisite programs?

MS. FOREMAN: How -- yes -- how FSIS will define prerequisite programs. They are pretty specific here about what it's not. But I don't know what it is. So I think my first suggestion to the agency has to be you've got to give us a definition, because it's hard to move forward without that.

MR. MAMMINGA: Okay. I think that that would be a very good place to start our first footchart, if you would,

because that is the very first question the agency asks us. And the very first question they ask us is what is the committee's reaction to agency thinking? Did you get that?

MS. FOREMAN: Yes.

MR. MAMMINGA: Okay. So the first thing that Carol offers is that, well, if we're going to understand your thinking, you had better define prerequisite programs for us. Is that right, Carol?

MS. FOREMAN: Yes.

MR. MAMMINGA: All right. Okay. Do we -- I don't know -- it's hard to make a forum for this discussion. But, again, going back to that contentious issue that I brought up, it seems to me the heart and soul of what the industry petition involves. There are some other issues in there that FSIS probably isn't going to give any ground about at all.

They probably made up their mind we can tell them whether we agree with them or not. But the idea that you can take what you told us, hey, I've had practice in this, I had this whole system before me, and I think I can come to you now, FSIS, and say, if I have this and this and this and this, along with my HACCP plan, at this particular point in the process and that HACCP plan is not a CCP. Now, isn't that the heart and soul of this?

MR. NEAL: And it boils down to this, if you don't

mind, Charles, that you could probably ask anybody who has plants or works in plants that we know what -- you know, I understand they have to define it. That's very important here, because they are kind of vague about it. But the bottom line is we know exactly what they are talking about.

And if they go around and define it and talk to industry or anything else, they are going to come up with Charles' answer right there so we know. So we would be against this thinking for the simple reason if there was a problem, as they are talking, and they are saying it frequently goes across product lines, so a list hasn't been in effect long enough to see where it frequently goes for one thing.

The other thing is if it does and it has to become a CCP, I don't believe anybody in industry, as long as they are being fair about it, you know, if it's cooling or, you know or not sanitation, but cooling or product contamination or adulteration or whatever, then it has to become a CCP. That's really common knowledge. And so if it has to be that, we understand that and have no problem with that becoming. Do you, Charles --

MR. LINK: No.

MR. NEAL: -- in your plant? I mean, if it is one is likely to create a hazard or likely to occur then, you know, we would do it automatically without any argument or

fight. I'm pretty sure I speak for most anybody.

MR. MAMMINGA: Okay, John. Tell me again in this issue about a combination of the whole system, starting with the prerequisite programs going into the development of a HACCP plan where you do a hazard analysis and you identify your customers and your products and right through flowcharts and everything else.

In your mind, can you take that whole ball of wax and then go to a point in the process, a point in that process and say, well, when I look at my prerequisite programs, when I look at all the development I have done into carrying out and validating my HACCP plan, I could really say this might be a CCP for other people, but it's not for me. You think you can say that?

MR. NEAL: Well, different products have different involvements.

MR. MAMMINGA: But are we even talking a probability here?

MR. NEAL: Yes, yes.

MR. MAMMINGA: Elsa, you haven't said anything yet. Get in here. You're a teacher and tell us what you think.

MS. MURANO: I was saying -- I'm trying to think -- Not having read that OIG report. And I think what is a concern, you know, let's say FSIS defines prerequisite

programs as GMP's and so forth, if those GMP's and whatever other procedures that FSIS defines as a prerequisite, if those have the requirement to be in place that they have to have a piece written for those, that when you violate your prerequisite programs, there's a corrective action and so forth and so on.

In a way, parallelling what happens in a HACCP plan, I think we're going to find that for some people what is covered by a prerequisite program is covered well enough and documented in a corrective action and all that in a very similar way as what HACCP would do that in that situation, then it's clear, then, that you don't have to have that as a critical control point.

And sometimes, in fact, years ago people used to say, well, that's a control point, not a critical control point. And that's where we started to split hairs. So to me, we can call it HACCP. We can call it prerequisite programs, as long as the bottom line in what we have is documentation, monitoring, corrective action if something happens that goes wrong. I mean, isn't that what it is?

It doesn't matter what you call it. That's what we're talking about. As long as everything that you do in that operation is documentable and monitored and the corrective action is verifiable, that you have control over and so forth, whether you call it a GMP or you call it a,

you know, a HACCP, it doesn't really matter, you know.

MR. MAMMINGA: The difference here is that we're making a quantum leap, in a sense --

MS. MURANO: Right.

MR. MAMMINGA: -- because when you don't even recognize prerequisite programs, when all you're interested in is SOP's, HACCP plants, performance standards that we have, obviously, no documentation was required.

No records were required to be kept, then so now we're taking the step and saying, well, okay if you keep records, if you do document, if you do have all of this information, then the agency said to us today, well, we might consider that that whole ball of wax tied together through a HACCP plan, the development of the same and the validation of the same, but that may take care of it. Now, in Mike's plant versus John's, I'm not too interested in doing some of these other things.

MR. NEAL: Right.

MR. MAMMINGA: All I want to do is what the government tells me I have to do might not work for me. Would you agree with that?

MR. NEAL: Yes, I would.

MR. MAMMINGA: Okay.

MS. MURANO: How does that sound to you, Carol? Do you see what I'm saying? If you take away the labels,

HACCP or whatever, take that away, what is it that we're talking about that we want people to have absolute control and so forth over?

MS. FOREMAN: It's more than the control. Mike started that. OIG -- and I'm going to read you a couple of things that they criticized about having prerequisites in this -- but it is whether, ultimately, the government has enough control to be able to put the stamp on at the end, to justify putting the stamp on at the end of the process.

And OIG's general feeling was that USDA had been too lenient, too loose in having companies set up their HACCP plans. And it made a couple of -- it made three specific -- listed three specific concerns about prerequisite programs.

And you'll see where they are coming from that FSIS has no assurances that prerequisite programs have been adequately developed and implemented, that prerequisite programs don't require documentation. And that's really for second, third, fourth, and fifth to show they'll prevent a specific hazard. And FSIS's oversight is limited by the scope of the plant's HACCP, because inspectors review only the HACCP records. So you can see it's --

MS. MURANO: We'll have to change all of that to answer those, yes.

MR. MAMMINGA: I think you hit the nail on the

head. I think OIG is telling FSIS why didn't you recognize prerequisite programs? Why didn't you make that a part of your whole system?

MS. MURANO: But they didn't recognize that you better --

MS. FOREMAN: Well, that's what Pat was saying this afternoon. She agrees with you completely.

MR. MAMMINGA: Well, you've heard me correct that.

MS. FOREMAN: And, in fact, now that I've gone back and looked at this -- and, unfortunately, I haven't -- the report weighs five pounds. I don't like it. It weighs more than my computer.

There's much to be said for what the agency's thinking is, putting prerequisite programs into a separate section of 415 and not lumping them in with 16 or 17, creating them as a separate section there, and requiring that those records be made available.

So, Pat, now that I sat down and went through this again after our discussion, I at least think that you're -- I think that you're -- if you want to go this way and, maybe, that's what OIG was saying, I think that you're setting it up in a way that meets their and my demands for accountability. But let you keep having them.

MR. LINK: Can I just throw a monkey wrench in the works or whatever? What difference does it make if -- I can

point out also all of what you will -- but if I, in my hazard analysis and my HACCP program, I say I do these things, a, b, c, and d, what's to preclude the USDA from going to look to see if I did a, b, c, and d?

And if I'm not doing it, then, you know, I'm guilty. But if I am telling you I'm doing it, why can't you all look at that? And why do we have to develop a new regulation to come up with something I already told you I'm doing?

MS. STOLFA: The training -- and this goes back to the original HACCP training. We told inspectors to limit their records review and verification to HACCP plans. And we have -- we don't know. In certain cases, we don't think there's a problem. And, in fact, establishments say, sure, you can look at this, et cetera. We don't think that's uniformly the case with --

MR. LINK: They allow you to see the records you mean?

MS. STOLFA: Yes, in GNP's. And unless we have a regulation that requires the creation of certain types of records, I mean, you can have them any way you want. And it's very difficult for us to manage our work force and to train them and to bring some orderliness to inspection oversight under circumstances like that.

MR. MAMMINGA: The long and the short of it is

those of us in government have to have some legal authority to demand something. And the HACCP rule, as it was written, not recognizing prerequisite programs (a) you didn't even have to have them; (b) you didn't have to keep any records and document that activity and; (c) you didn't have to show anything to us if you didn't want to. So --

MS. MURANO: If you didn't have them -- if you didn't have them, then you were going to have the HACCP plan from hell.

MR. MAMMINGA: Exactly. And there are a number of those out there --

MS. MURANO: Right, exactly.

MR. MAMMINGA: -- where people have struggled and continue to struggle, because they are trying to walk around on one leg.

MS. MURANO: Yes.

MR. NEAL: And that comes a point, without getting into a long, drawn-out emphasis -- there's no need to -- but the bottom line is if you have a criterion and you set it up, and the FSIS flaunts it, they should approve it. It's always developed by us, developed by this. There's no approval.

I mean, they go by it and look at you every day, but they never say, well, I'll approve that. Yet, they come check the records and everything's fine. But I will not

approve a plan. I cannot approve a plan. I'm thinking why.

MR. MAMMINGA: And don't you remember when --

MS. FOREMAN: But the National Advisory Committee said HACCP --

MS. MURANO: Microbacteria.

MS. FOREMAN: Thank you.

MR. MAMMINGA: That's good enough to perform the task.

MS. FOREMAN: Said you cannot have the government approve a HACCP plan. That's contrary to the concept of HACCP.

MR. MAMMINGA: And you can't demand any CCP's, because that's contrary to the point.

MS. FOREMAN: Frankly --

MR. NEAL: They don't have to demand it.

MS. MURANO: They don't have to demand it. But it would be nice if they could, yes, this looks good.

MR. NEAL: You've covered everything, and it looks good.

MS. FOREMAN: But before they can do that, there has to be a standard written for what the inspector can approve. That's the way of government.

MS. MURANO: And that's the problem.

MS. FOREMAN: And, you know, maybe you ought to consider whether or not we want to go back and say, all

right, have the government approve the basic HACCP to begin with. I know that it's contrary but, you know, HACCP is not a religious experience.

MR. LINK: But, you know, we did actually do that. And you don't need to call it approval. But we had to sit down with the USDA and go through saying do we have this, this, this, this.

MR. MAMMINGA: Well, they said no. They said do we not have.

MR. LINK: Do we not have.

MR. MAMMINGA: No, no, no, no.

MR. LINK: We'll tell you some things that we're -- well, you don't need this or you don't need this. They won't tell us that. But, you know, like I say I don't necessarily agree with that one because, quite frankly, I want to be responsible for it. And my plan may not look like your plan. And I don't necessarily want Pat telling me it's got to look like your plan.

MR. NEAL: Well, are you talking to me? You talking to me?

MR. LINK: Okay. That's us. No. What I'm saying is I understand that. And I know it's a fine line not to tell you. But if it comes to the point when you're done with it and they are reviewing your records and checking it, I mean, it must be acceptable is what I'm saying. They

don't have to approve it. But it must be acceptable at that point.

MR. MAMMINGA: It has to meet --

MR. LINK: And as long as you meet everything there, then it's acceptable, you know. I don't want to get in an argument about it.

MR. MAMMINGA: Would you agree that if the government would define prerequisite programs and if the government would specify what documents were appropriate to verify the activity, that then you could step back and look at the whole picture and say here is my whole plan?

And through my risk analysis, I have decided that I do not have a hazard that is reasonably likely to occur here because of this and this and this, all of which I document and keep track of. Would you agree to that?

MR. LINK: Yes, as long as it isn't too definitive on what a form has to look like.

MR. NEAL: Exactly.

MR. LINK: Similarly, HACCP is there's several things you've got to get done and you've got to document it.

MS. FOREMAN: Look at on page five, the paragraph that's labeled number four. Is what they are saying is you can have prerequisite -- having them would be voluntary? But if -- but to have a successful one, it has to be verifiable. You've got to have records be available to them

and so forth.

MR. LINK: I'm comfortable with that.

MS. FOREMAN: You comfortable with that? I have one question about that last phrase down there about the prevention of a pattern of noncompliance, because I can never figure out what happens if you find a pattern of noncompliance. But --

MR. MAMMINGA: Well, you know, that's something that people like myself are supposed to hit on, again, based on the reports and the PBIS summary information that I get on the PBIS system.

We ought to be able to hit that pattern of noncompliance with the trend indicators off the noncompliance record, you know. That's what we do. Somebody's got to say four is okay, but five, that's it. We're drawing the line on that, because now we have a trend indicator that shows this is a process out of control.

MR. LINK: And I think part of this, though, in the program itself, you're going to document at what point I need to do something. Okay. I messed up today. Oh, well. But if I mess up every day, then I need to be doing something. So the responsibility's got to lie at the plant, too. And I agree, from the regulatory standpoint, the agency has to come in at some point and say you haven't done --

MS. FOREMAN: They've got some plants out there that don't know how to set up a critical control point. And --

MS. MURANO: That's true.

MS. FOREMAN: -- some of them got one in the whole plant. And so, you know, you know what you want to do, and you don't want to be constrained in doing it by having stuff written on paper. But then you've got these other people that don't know how to do it, unless it's written.

MR. LINK: Well, I recommended a guidance document. And that quickly becomes a regulatory document. So I'm scared to say that.

MR. MAMMINGA: Well, you know, but there's a practical part of this. The very first time I went to HACCP school in 1995 and they gave us a beef slaughter process, when we were done with it, we had like 86 critical control points. If the guy looked at it, well, clean your glasses, you know, and things like that. And it got to be -- we went to the sublime to the ridiculous.

So you've kind of got to ride the bike a little bit to see, you know, there is a -- that's why you come back, everyone is specific to the plant. Some plants have challenges that are different than others. It could come down to employee and language problems, not necessarily anything to do with the facility or their good intentions.

So you've got to tailor these things. But --

MS. MURANO: I remember teaching a HACCP workshop to a bunch of inspectors from other countries. It was here in D.C., part of WHO activity. And, you know, when we teach HACCP workshops to industry here, you don't consider the portability of the water, because that's part of a prerequisite thing. You assume water's potable but not in those places.

So when we would be doing this workshop they'd -- these guys would put that as a CCP. And I'd say, well, you're wrong. And they'd say, well, no, we're right because we live in those countries. And that is a CCP. And they are right. They are right.

MR. MAMMINGA: This book has an example of a prerequisite program that could affect the hazard analysis. And I think it's kind of common, everyday, practical stuff for even a small plant.

And it says in here, for example, "Many establishments have preventative maintenance procedures for processing equipment to avoid unexpected equipment failure and loss of production." Now, that's an economic issue, that isn't food safety at all.

It says, "However during the development of the HACCP plan, the team may decide that certain maintenance procedures could be documented, a record kept of them, along

with the calibration, and may decide that certain maintenance procedures, along with the calibration of its temperature, should be included in the plan as verification activities. This would further ensure that all food in that oven is cooked to the minimum internal temperature for food safety."

Now, that would be a good thing. If I could get some of these small plants to have a maintenance procedure, an SOP for equipment maintenance that could tie directly, it won't take away the necessity for thermal processing as a kill-step. It won't take away the fact that that -- no.

But what it's going to do is it's going to give some validity to the idea that you can tie more than one thing together than just the thermometer that's sticking in the product. So that is what I would envision as something that could be of great benefit to industry.

MS. FOREMAN: And this is maintenance, not sanitation?

MR. MAMMINGA: Exactly. It's how often do we --

MS. FOREMAN: It's a very good example. That's a good illustration. And we ought to use that tomorrow, regardless of where we end up.

MR. MAMMINGA: Okay.

MS. FOREMAN: I think that makes pictures in peoples' heads.

MR. LINK: And in that case, CCP's still in place.

MR. MAMMINGA: I mean, we're going to have thermal processing no matter what. And we're going to document that. But it's like another layer of protection in that we have a written SOP for maintenance of our equipment. We keep records that we did it and what we did. That, tied together with our minimum temperature of 158 degrees Fahrenheit, shows that we have this kill-step covered. It makes sense. It's a good thing, I think.

MS. MURANO: These plants that have, like he said, one CCP, do you think it's producing unsafe products? We don't know. But let's say that they are not, why aren't they? And --

MS. FOREMAN: Yes. The inspector still keeps it from going out the door, because we're living with, you know, an uncomfortable marriage of old and new here.

MS. MURANO: Yes.

MS. FOREMAN: So --

MS. MURANO: Yes. I was going to say --

MS. FOREMAN: What would you say, Pat?

MS. STOLFA: We did some survey work of slaughter plants, in particular, where the number of hazards identified ranged from, I think, one was the lowest. And then we had one that was an 88. And the number of critical control points was one in virtually every case in that they

were livestocks.

But when they were livestock slaughter plants, I attribute that to exactly what Carol's talking about. We still have inspectors standing and looking at every carcass coming by as they -- it goes, you know, reaches the end of the railing. In the case of poultry plants, I think the situation is a little different. But I think that certainly it was an example of what Carol said.

MS. MURANO: I guess because I'll submit to you that, besides that -- and I agree with that -- I think that's probably a main reason why they are not producing safe food. But it's probably also because they are -- they have prerequisite programs, whether they call them that or not, you know.

Remember the example I gave about that plant, you know. That's not how I'm sure those places operate. I hope not, anyway, because there's an inspector there. They couldn't possibly have those practices because the inspector is there. So they have to have these prerequisite programs, even though they are not recognized.

So, to me, a place like that if you have these prerequisite programs and you require that records are kept and all that kind of stuff, you kind of elevate the importance of what they are already doing, if anything.

And you make them think that, okay, you may think

you have one CCP and you may get away with it, but then you have to do this to make up for it, which is to keep strong records in your prerequisite programs. But not recognizing the prerequisite programs makes these people not even give that a second thought.

MS. FOREMAN: I think that's a good point. Let me just ask, John, you don't have an inspector in your plant all day, do you?

MR. NEAL: No.

MS. FOREMAN: Aren't you on a patrol basis?

MR. NEAL: Yes. But I have them three days a week.

MS. FOREMAN: They only come three days a week all day? Do you come all day or --

MR. NEAL: Well, the reason why they come those three days a week is those three days a week I'm processing.

MS. FOREMAN: Okay. Fine.

MR. NEAL: That's why they are there.

MR. MAMMINGA: You opened up a big can of worms there.

MS. FOREMAN: Don't ever say that to me.

MR. LINK: I may be dumb, but I'm not stupid.

MR. MAMMINGA: I'm just fooling.

MR. LINK: I know that.

MR. MAMMINGA: They haven't shot any of us for

that.

MR. NEAL: We don't have any inspectors, no.

MR. LINK: Do they stay all day?

MR. NEAL: Huh?

MR. LINK: Do they stay all day?

MR. NEAL: Usually not. It depends if she has something else to do or Dr. House has something else to do. They stay pretty busy in the patrol. But they will attempt to be there.

But at the same time, in their defense, I will say this: If something comes up, they have a problem at some other plant, I think -- and I don't know how far this -- how deep this goes -- but I think that they know that they walk in, our plant is not -- you know, maybe you get the gold star. It's not as specific a problem, maybe, as we were overdue in the meat or stuff like that where the boys are.

They will stay at that problem plant and not be there for some reason, and we'll go ahead and do the meat and do everything just like we normally did it, go through our HACCP plan, do it the same way every time. And they are not there, and they might come in the next day and say what did you do? And I said, they did about this much beef, this much bacon, this much hams. We got some stuff in here today. And this is what we're doing.

And then she looks over the records and she seems

to go away happy. And she's pretty thorough. She's a -- she's not a flaky one, you know. No offense, but everybody has them. I don't care what industry or what job you have, we have slackers in our work force. And he does. We all do. And that's just a fact of life. Some are better than others. And she's pretty diligent. I miss something, she lets me know it.

MR. MAMMINGA: Okay. Good.

MR. NEAL: But that's an example.

MR. MAMMINGA: Sure.

MR. NEAL: And that's my gold star, you know.

MS. FOREMAN: That's a good point, except that your customer doesn't know that.

MR. NEAL: Well, my customer has trusted me for 60 years. That's the history.

MS. FOREMAN: Yes.

MR. NEAL: And we've been through the history deal already.

MR. MAMMINGA: Unfortunately, in all of our work, we can be on top today and looking up from the gutter tomorrow. Every night I go to bed, I say please, God, let nobody get sick for the best of intentions.

MR. NEAL: I understand.

MR. MAMMINGA: Have we kind of cued through the prerequisite programs?

MS. FOREMAN: Yes. And I would be, as I say, I'm reasonably comfortable with the notion of defining these and putting them into a separate section with the kind of requirements that the department has said that they -- the kind of structure around which you would build it. But you've got to define it.

MR. MAMMINGA: Well, of course, the department has said it's going to be voluntary. So those people that choose not to, they'll have to struggle along the way they have. Wouldn't that be correct?

MS. FOREMAN: Yes.

MR. MAMMINGA: So we're just saying if want to go the extra mile to develop the way the agency has asked you or offered you, then you can consider the whole nine yards in your hazard analysis and the development of your HACCP program.

MS. FOREMAN: And as a reward for doing the voluntary program, you have to let the government --

MR. LINK: That's a reward?

MR. MAMMINGA: Would it be all right with the rest -- there are some folks in here that are pretty smart. And if anybody in the audience has a burning feeling about this particular thing before we get off of it, could I hear it, because we'd like to know. Anybody?

MR. DOPP: I'll just make one comment. I did a

lot of HACCP training and HACCP auditing and been in a lot of plants, seen a lot of the plans, and I was in one one time where we were helping the individual meet the regulatory requirements because of a deadline coming up, and all they really had was the HACCP plan, but didn't have all that prerequisite stuff to go with it. And a couple of years later, they looked at, as we had to go back and rebuild our whole program from the ground up, because it wouldn't stand there by itself.

MR. MAMMINGA: Very excellent. That's a very excellent point.

MR. DOPP: And I think that's a good example of the importance of those prerequisite programs.

MR. MAMMINGA: And we are kind of going back and cleaning house a little bit, because we should have done this in 1995. This should have been a part of the program in '95, as far as I'm concerned. What do I know?

MR. DOPP: There wasn't even time then.

MR. MAMMINGA: Well, you're right.

MS. MURANO: I mean, that's what the SSOP's that had to be there.

MR. NEAL: Yes. That was the first one to be in was the SSOP's.

MS. MURANO: That's, in fact, that's --

MR. NEAL: I remember that coming in telling me

that.

MS. MURANO: That was necessary. Whoever thought of putting that in, that's basically what they were doing was --

MR. MAMMINGA: Okay. All right. I just wanted to make sure we had Bill's cards to hand out, that we got it done properly. That kind of, if you look at the issue paper, that kind of -- Carol, do you really want to try to tie this example that I read out here into that summary?

MS. FOREMAN: No. I just think that when you make the report to the committee tomorrow that you might use that as a description. I don't think it has to be written in. But that's a -- that makes --

MR. MAMMINGA: Okay, okay. So --

MR. HONTZ: Could I --

MR. MAMMINGA: Yes, you bet. Sure.

MR. HONTZ: In regard to prerequisite programs --

MR. MAMMINGA: Yes?

MR. HONTZ: -- it seems to me that there has to be a distinction. If you're going to allow a prerequisite program, there's an assumption that a minor deviation or an occasional deviation from that normal requirement does not represent a safety hazard, as opposed to a critical control. A HACCP plan with a deviation does require you to do something with the product.

MR. MAMMINGA: That's a very excellent point. You estimate --

MR. HONTZ: It's in the paper.

MR. MAMMINGA: It's here.

MR. HONTZ: The point I wanted to make is that if we're drawing a distinction between the level of risk involved with that CCP versus a prerequisite program, then it makes sense to me that there be a distinction in the level of attention -- the level of attention to details and recordkeeping and whatnot that the agency would need to exert over that, as well.

So what I would not like to see is the agency all of a sudden, because they had a new reg that allows for prerequisites, for them to spend all their time looking at records, even with prerequisites which are not of themselves food safety hazard issues.

So when we talk about continuous access to all of the prerequisite documentation that might be kept, it would seem to me that there would need to be some moderation in regard to the -- we're not disagreeing that records and documentation wouldn't need to be available.

But I would think that for a prerequisite program, that perhaps would not the best use of resources for the inspector to be looking at prerequisite documentation, as opposed to the HACCP critical control aspect they ought to

be devoting the bulk of their attention to.

MS. FOREMAN: Proportionality.

MR. MAMMINGA: In the example I gave from this book where you have a maintenance SOP, they give credence to your critical control point monitoring and recordkeeping by saying, hey, folks, here's my maintenance schedule. This is how we maintain this equipment. So we have confidence that this is, you know -- I guess, I think, we're all in agreement that we're not going to substitute. We're going to enhance.

MS. FOREMAN: Oh, yes.

MR. MAMMINGA: Is that about how we look at it? We're substituting and we're enhancing our food safety. We're enhancing the validity of our CCP's and the monitoring and the recordkeeping. We're enhancing that by having this prerequisite program in place. Does that sound about right? All right. Anyone else from around the room? Pat, do you have anything to say about our thoughts on that? Okay.

Let's go on and if I get off track here, the issue paper, I seem to think that we're on -- that the agency has carefully considered the petition for requested changes to the key HACCP system in 417, specifically the changes in the definition of food safety hazard, hazard analysis, and severity. And the agency did not respond positively. I'll tell you, I would be very grateful if one of you would

explain the petition on that point to me. Anyone feel up to that?

MALE SPEAKER: Go, Charles.

MR. MAMMINGA: What is this petition?

MS. FOREMAN: If you look at the petition, it, you know --

MR. LINK: Using the example, people contamination.

MS. FOREMAN: Well --

MS. STOLFA: The petition has specific actions.

MR. MAMMINGA: Too many documents. I was on the wrong document.

MS. MURANO: I think part of it is first was they wanted to follow the definition of the 1997, you know, HACCP document. But also because there's no prerequisite programs, essentially, it's in the petitioners' minds the need to define hazard as being likely or not likely, which is what the 1996 document -- by those prerequisites not being there, they feel like, well, now we have to really make sure that people understand what the right definition of a hazard is. I don't think this is as important anymore as we've got --

MS. FOREMAN: That's a good point. That's an interesting take on it, because I thought of these as really separate issues included within the petition --

MS. MURANO: Yes, which just kind of occurred to me.

MS. FOREMAN: The microcommittee's definition of a hazard is a biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control. The rule defines a food safety hazard as any biological, chemical, or physical property that may.

And as far as I can tell, what you've got here is a difference that reflects the law. And the law says -- I think that the rule is a closer read of the governing statute.

MS. MURANO: Yes.

MR. MAMMINGA: I don't know the law. But I know that when I'm going through a process and trying to figure out if there's a hazard here, I can come up with a lot of stuff that might happen, you know, a meteor might hit. But I have to take into consideration is it going to happen or not. And if it does happen, how severe is it.

I mean, I've really got to think about is this hazard something I need to be worried about or not. And USDA's definition doesn't give me that latitude. It says, well, it may happen. Deal with it.

MR. LINK: Just like with the CCP's, my glasses may get something on them and I may not see it.

MR. MAMMINGA: It hasn't happened. You can get

someone's glasses and not see that.

MR. LINK: That's right.

MR. MAMMINGA: That's exactly -- I mean, I don't know the law. I don't know the law.

MS. FOREMAN: Well, as far as I can tell -- and let's ask the agency people -- my assumption was that you were -- that the petition was looking to get closer to the microcommittee's definition, and the agency feels constrained to stay as close as possible to the governing statute. And this is an issue that we've thought about over the years.

For example, you might argue that having the industry median level of salmonella contamination is not reasonably likely to cause me to get sick, but it may cause me to get sick.

MR. LINK: That's right.

MR. MAMMINGA: Is that the issue here, may versus reasonably likely?

MS. FOREMAN: That's how I read it. But I have to see if the agency folks think that's the big deal.

MR. MAMMINGA: Pat, we really could use some guidance here.

MS. STOLFA: We believe that the petitioners' request makes the -- brings the need for more judgment to the interpretation than we're comfortable with. And I

essentially think I'll agree with it.

MR. MAMMINGA: And I think, then, that may is easier to interpret amongst us all versus reasonably likely for us to interpret. Is that the case that we're talking about?

MS. MURANO: And I think you're right, because if it requires that you have some kind of background in this area to make that judgment call, I mean, it really does. You know, we tell industry you need to talk to --

MS. FOREMAN: Erring on the side of safety instead of assuming -- instead of saying it has to be reasonable, it's saying you've got to think about it might.

MS. MURANO: Yes.

MR. LINK: And we have. But it might --

MS. FOREMAN: Apply to the moon.

MR. LINK: -- apply to the moon. But I've got to go to the CCP for that. And I think --

MS. STOLFA: No, you don't have to do that.

MR. LINK: I know. But when you go through a hazard analysis and you're really thinking about everything that can happen, it's the only thing you can come up with. But they are not likely to happen. And that's --

MS. STOLFA: Approving the establishment, the concept of approving the establishment and whether approving the establishment would apply controls.

MR. LINK: And all we're asking, I think, in the petition is to go down the same path you're trying to go down with risk-based decision-making and think about what the risk and what the severity is when you decide is there really a hazard there. We'll be glad to help train, you know.

MR. NEAL: Can I add something of a -- Elsa? Excuse me, Charles. When you each have a HACCP program, when they make a hazards analysis, what's one of the blocks in hazards analysis?

MS. MURANO: Likelihood -- likelihood of severity.

MR. NEAL: Likely to occur?

MS. MURANO: Yes, absolutely.

MR. NEAL: And not to --

MS. MURANO: And I'll tell you, though, but when we do these workshops, people wrestle over that and argue. Some people in a group will say, well, it is likely. And other people say it is not likely. So --

MR. NEAL: Well, may is so vague. I mean, it's like saying it may occur some day. But reasonably likely is specific. If I was a layperson on the street, got mad, got sick, or let's say let me see what these things say or you know how people are, I'm sure in Washington they come to meetings. Do people like that just come to meetings and listen and I'm more concerned with your -- I can't say

irradiation?

MS. MURANO: Yes, sir.

MR. NEAL: That gentleman was asking about it today. I mean, no offense to him, but he has a concern of some sort. But he's likely to be the guy that looks on here and if I saw reasonably likely to cause illness or injury in the absence of this control, I would think that's specific. You know, that means -- but may doesn't say much. That's my feeling, you know.

MS. STOLFA: The language in the regulation is now reasonably likely, food safety reasonably likely to occur.

MS. FOREMAN: That's right.

MS. STOLFA: And the regulation goes on to define what that means --

MR. NEAL: Okay.

MS. STOLFA: -- in regulatory language. And we are, you know, we're a regulatory agency. We don't -- you know, we're not a training agency. We're not any of those things. We're a public health regulatory agency. And so we need to have regulatory concepts that work for us and that can be implemented by our work force.

MR. NEAL: Okay. I understand that, yes. I'm not, you know, opposed.

MS. MURANO: And, you know, you've got to consider sometimes, you know, these things change. Pathogens have a

way of surprising us, you know. And sometimes, you know, we go for a long time and we say, well, it's not likely to occur, but then here comes all of the 787 who have the acid tolerance. And who knew?

MR. LINK: And you have to figure out something's going on.

MR. MAMMINGA: In all of HACCP, there's no point that has caused more heartburn than this one, because you know the agency goes, well, we're not going to tell you. But then they tell us.

And this comes into that point that I always talk about of what the government's going to do what it thinks it has to do. And that is for social and scientific and political and other reasons they make decisions to do things that are not necessarily science. But, you know, lines are drawn in the sand.

MS. FOREMAN: Well, I think the reality is if you want to sustain public support -- I was surprised at this proposal. I really was because if you want -- this is still a fragile entity out here. The public has not bought it yet. God knows the Inspectors Union hasn't bought it.

And you want to come in and say we can go from may to reasonably likely is several steps down the ladder in terms of what you're required to do to protect public health. You don't want that story on the front page of the

Washington Post.

MS. MURANO: No, that's right.

MR. MAMMINGA: Well, I understand.

MALE SPEAKER: Well, Mark's got the regulation out.

MR. DOPP: Yes. The definition of food safety hazard is any biological or chemical or physical property that may cause a food safety -- a food -- excuse me -- in food safety in human consumption and is not reasonably likely, but may. It may --

MS. FOREMAN: But the petition urged that it change.

MR. DOPP: To reasonably likely. And we did that because -- you're right. We did it exactly for the reason identified and that is -- and as one of the people who basically wrote the petition, we did it because we believed it would be important to be consistent with the '97 document, the '97 National Hazard Committee paper.

And there's one other point. The statute says may for products, for substances that are not naturally occurring. There's a different standard for whether a property is adulterated if the substance is naturally occurring. And it is a --

MS. FOREMAN: Ordinarily.

MR. DOPP: It is ordinarily not injurious. It is

a less onerous standard for not for naturally occurring substances. So you can't say that it's strictly speaking in compliance with the statute, because the statute has two different standards, depending on the nature of the substance.

MS. FOREMAN: That's true. The department erred on the side of caution in writing it. And, again, you can -- if you want to have HACCP as a private entity, a quality-assurance and safety assurance that each plant gets to do on its own terms, that's one thing. If you want it for a plant to qualify to get the seal that says the United States Government says this product's been inspected, then I think that you have to agree to a higher standard.

And the government erred in terms -- on the side of choosing the higher standard, not the lower standard. I wouldn't say erred. They made a choice. And I've got to tell you that if you want -- you know, decide if you can live with having the front page of the Washington Post say the Department of Agriculture decided it would opt out of the higher standard. The tougher one may cause somebody to get sick to it's reasonably likely to cause a problem. You can't live with that.

MR. MAMMINGA: Give a perspective.

MALE SPEAKER: I was going to break it down, as Mark has -- petition and --

MR. MAMMINGA: Okay. Thank you. To me, you know, it's -- I don't have a personal feel for this from what I do for a living. Wordsmithing is not my game. And I agree with Carol there are inferences. And if the everyday person doesn't get them, others will tell them. That's just the nature of our business.

We explain what to do all the time. So I don't have a feel for it, folks. May or reasonably likely, when you're talking about human destruction and death as the possibility, what term could we possibly come up with that would adequately illustrate what we're trying to do? May, reasonably likely, we don't want to have it happen at all.

MR. LINK: I think every day, we make risk-based decisions. We decide to step out in the street. You know, I might get hit by a car. But, you know, if I look and I'm prudent, I won't.

MR. NEAL: We're taking this upon us to do this. I mean, we're taking the brunt on us. It's not on you all.

MS. FOREMAN: But it comes to me with a sign on it that says the United States Government says it's been inspected and it's safe.

MR. MAMMINGA: So, Carol --

MS. FOREMAN: You want to do away with the USDA's seal, we can talk about some very different standards.

MR. NEAL: Well, no. I understand that. I'm not

knocking that. But are you putting it in the standpoint of -- is it a USDA decision, a union-based decision? I mean, you were talking about --

MS. FOREMAN: What's it got to do with the union?

MR. NEAL: Well, you said something to the effect that the union -- that it affected the union, that the union didn't agree with this --

MS. FOREMAN: No. Wait a minute.

MR. NEAL: -- a minute ago --

MS. FOREMAN: No.

MR. NEAL: -- with this statement here.

MS. FOREMAN: No. I said the -- nothing to do with the union, zero to do with the union.

MR. NEAL: Okay.

MS. FOREMAN: The law says that there are two standards here. The government decided to take the higher standard in this case.

MR. NEAL: Right.

MS. FOREMAN: And what I said was you don't want it to appear on the front page of the Washington Post. I'm not talking about the union. Hell, I'll go give them the story --

MR. NEAL: Okay, okay.

MS. FOREMAN: -- that says the government decided that it had to be reasonably likely to make you sick. Now,

Nancy Donnelly's who's kid died of E.coli poisoning isn't here at this meeting. But you don't want to have that discussion with Nancy. She wants it to the standard to be "may." She lost her only child.

MR. NEAL: Well, I lost a child, too. I'm very sympathetic.

MS. FOREMAN: What?

MR. NEAL: Yes, we lost one, too, very strange circumstances, our first-born. And he was six years old.

MS. FOREMAN: Well, you know what it's like.

MR. NEAL: I understand Ms. Donnelly's situation. Believe me, I have five children and my heart truly goes out. It's an awful experience. But it's a tough deal to be taken personal.

MS. FOREMAN: But you're not --

MR. NEAL: I'm not fighting with you.

MS. FOREMAN: You're not going to do a thing differently because of this language. And some of your brethren who aren't as fastidious might.

MR. MAMMINGA: What are the ramifications? Someone explain to me what are the ramifications of may versus reasonably likely? Now, I admit up front may appears --

MR. NEAL: Let's talk life or death.

MR. MAMMINGA: -- and my understanding of the high

man --

MR. NEAL: And I don't mean to be that way or anything else.

MR. MAMMINGA: But what is a practical example?

MS. FOREMAN: Well, I think you'd have to prove that --

MR. DOPP: I'd be happy to give you an example.

MR. MAMMINGA: Give me one.

MR. DOPP: When I did private practice -- and this actually got appealed believe it or not -- when I did private practice representing a company and believe it or not the inspector came in and said, well, what if an asteroid or a meteorite hits the cooler, how have you accounted for that possibility, because it's possible? It may happen. Now, is that absurd?

MR. MAMMINGA: Sure.

MR. DOPP: But that is a true story that actually happened. And they had to appeal that position from the inspector about having something like that put into the plan as a CCP.

MR. MAMMINGA: But the -- it was not upheld, was it?

MR. DOPP: Ultimately, no. But I bet you can find circumstances throughout the country with things -- other lists are still in effect.

MS. FOREMAN: I'm going to give you another example. You'd have to be able to prove that there was enough salmonella, and the standard would have to be is there enough salmonella in any given carcass to be reasonably likely to make somebody sick, as opposed to may make somebody sick. In other words, it would just completely disembowel performance standards for pathogens.

MR. DOPP: Except salmonella found in an adult --

MS. FOREMAN: I'm saying that when you have that language -- and you know it -- it's designed to say you couldn't ever enforce a pathogen standard, because that's the history of that provision in the law and the reason the department argued for years that they didn't have the ability to regulate.

MR. MAMMINGA: I've learned more about may and reasonably likely than I imagined to be honest, I don't want to make light of this.

MR. NEAL: I'm to do out --

MS. FOREMAN: We agree on one thing, though.

MR. NEAL: It's true.

MS. FOREMAN: We agree on one thing: May is the higher standard than reasonably likely. And that's why the industry wants it changed.

MR. MAMMINGA: Another half hour? Thank you. All right.

MS. FOREMAN: I have a couple more questions.

MR. MAMMINGA: Well, we have this one and one more, I guess. But committee members, you've been quiet down there. Come on to our side because you're smart. What do you think about this?

MS. BAYSE: I'm with you with reasonably likely. Can I just go just totally off for a minute and say something naive? I find sometimes if you sort of get away from the issue, somebody may have a thought. And it probably may be myself. I know this is naive, but suppose we come up with the prerequisite programs and a lot more paperwork for USDA?

You know, thinking as a person at a small college and teaching and the whole thing, you know, are there provisions now to provide funds for personnel to deal with these things that we're going to be recommending? How does that work?

MR. NEAL: In our plants?

MS. BAYSE: No, no. I mean the USDA? You go to Congress. You --

MS. FOREMAN: No, no. They've got more money than they want. We made more.

MALE SPEAKER: Are you disturbed by that?

MS. BAYSE: It sounds like --

MS. FOREMAN: It's the only government agency that

I've dealt with in 40 years here that gets as much money as it asks for every year and has the regulated industry out there on the hill saying give them whatever they ask for, because we can't open our door unless we've got on inspector in the plant. So --

MR. NEAL: Yes, that's true.

MS. BAYSE: Well, in doubt, we would say --

MS. FOREMAN: Yes, I agree with that. As a matter of fact someone is well endowed in that.

MS. BAYSE: Well --

MALE SPEAKER: Well, no.

MR. MAMMINGA: With a half an hour to go and I'm on the clock, could we agree that we disagree -- no. Let's say we agree that may and reasonably likely are the key words here that some of us think that 1 denotes a clearly higher standard than the other and that some of us do not?

MS. FOREMAN: Is there anybody that thinks may is not a higher standard? I think what Charles is saying is that he has to worry to death about is he going to be able to contemplate all the mays.

MR. LINK: And I'm trying to put a little more common sense into some of the decisions that are made based on risk.

MR. MAMMINGA: Based on reasonably likely?

MR. LINK: Reasonably likely, severity, saying

what the agency's saying they are basically not going there. But I'd certainly like to encourage that as we move down this road of risk-based decision-making and risk-based, science-based inspection that we, at some point, if we need to do is, to coin a term from the FDA of meat course correction, that maybe we ought to consider that.

MS. FOREMAN: Actually, you know, if we had the science to know what was reasonably likely in terms of pathogen contamination to make people sick, then you could be a little more precise in this language.

It's the absence of the necessary science that, in part, creates this problem. So I would certainly argue that keeping a higher standard is a way to encourage the generation of the information that we need to make the most intelligent judgment.

MR. LINK: Well, you're using salmonella as an example, we've been told what we have to do there. So we don't have to put --

MS. FOREMAN: I'm not sure it would be sustained if you changed that.

MR. MAMMINGA: Carol asked a question. I'd like to see its answer. Individually, as a group, do we think, individually now, how many of us think that may indicates a clearly higher standard than reasonably likely?

MS. MURANO: It's more sensitive.

MS. FOREMAN: More sensitive is probably a better word.

MR. MAMMINGA: And the two --

MALE SPEAKER: It pretty much depends on --

MR. MAMMINGA: But is that our collective thinking that may denotes a higher standard and that if may were changed to reasonably likely, as Carol suggests, that confidence might be lost in the system?

MS. FOREMAN: Reasonably likely.

MR. MAMMINGA: Carol, what do you think? I'm getting into my semideep thinking here.

MS. MURANO: Reasonably likely --

MR. MAMMINGA: Well, we ought to give the agency our thought. That's what they are asking for. And it seems like this whole issue hangs on may versus reasonably likely.

MR. NEAL: I know this sounds silly, but it has its effects just like may does, the same difference.

MS. MURANO: And lets's not forget what pat was saying that in the agency's thinking, changing that would require training, et cetera, of the inspector so that they can make that -- they can understand what that means. They can make the judgments. And, you know, that's another dimension to the whole thing.

MR. NEAL: Maybe, I'm too naive and don't what's in the -- but do you believe that it would the headlines

tomorrow if may and reasonably likely --

MS. MURANO: Yes, it would just look that way.

MR. NEAL: Would it be that big a issue --

MS. MURANO: Sure, it would.

MR. NEAL: -- over a martyr?

MS. MURANO: If it's explained.

MR. NEAL: I know how things change in Washington. I understand that.

MS. FOREMAN: And rolled back a higher standard to a lower standard.

MR. NEAL: I'm the stranger in town. And I wouldn't --

MR. MAMMINGA: Even George Anton (phonetic) from the Morning Register might have that on the back page of the business section. But it would be there. So if the agency has asked us what they thought, that's -- they have asked us to fix their problem. They've asked us what do you think of what we've said.

Well, we said, you know, in the best of our combined, collaborative effort that we recognize that same difference in may and reasonably likely. May sounds to be a more sensitive word and that a change in that could cause may, reasonably likely -- I don't know what the action word there is -- but that brings into question consumer confidence in the system.

MR. LINK: I don't necessarily agree with that. But, you know, it may, it could, it may.

MR. MAMMINGA: And --

MR. LINK: And I don't think we're arguing for a lesser standard. That wasn't the issue.

MR. MAMMINGA: No.

MS. MURANO: No.

MR. LINK: And you could debate the definition of may.

MR. MAMMINGA: Well, Carol has perception on that reasonably likely that I hadn't heard before. She said this very night, do you really think, Carol, that that is -- would be used by some unscrupulous people as an out?

MS. FOREMAN: Oh, yes. Sure, it would. Well, look, after somebody got in trouble, their lawyer would argue in court that they took care of something that was reasonably likely. And you could even argue that E.coli 0157 H-7 contamination is not reasonably likely.

MR. MAMMINGA: Okay. I'm willing to accept what I don't know. I mean, I have no reason to challenge it. Could we go on in what time we have left to take a look at this, the next paragraph on page two of the issue paper, the bullet that talks about enters commerce, shipped?

MR. DOPP: Mike?

MR. MAMMINGA: Yes?

MR. DOPP: There's something on that last point, because there was a concern about a training version if the terminology was train and if it changed. And I think there's a training burden in your way, because you have to have adequate training to get around the asteroid-type thinking that certainly exists out there.

MR. MAMMINGA: Doc, I think the challenge with keeping everybody up to speed on training, some days I almost cover my head up, because you wonder just how in these quickly changing times how can you keep everybody up to speed at their level? But that's an excellent point, training throughout. Pat, you said something today about produced when you talked about entering commerce.

MS. STOLFA: Right.

MR. MAMMINGA: I like that. I like produced, but what do you folks think about that?

MS. BAYSE: It's produced versus shipped? What's that?

MR. HONTZ: I had a question on your paper, Pat. Your language -- I don't have it in front of me -- but that you wouldn't mind taking interest commerce out of the regulation. Where in the regulations is that? Is that not the HACCP review?

FEMALE SPEAKER: Yes. We'll be very glad.

MR. HONTZ: It's true. It's true.

MR. MAMMINGA: What's that?

MS. STOLFA: Produced is our word. We think shipped is a distraction in some circumstances and the line of demarcation for when product is produced is after the establishment has performed preshipment review under 417.5C.

MR. MAMMINGA: I think that's a very excellent way. That way you can keep it here, send it down the road, put it in storage. It didn't make any difference. After preshipment review, it has been produced.

MS. FOREMAN: I thought that was a good way out of a hard squeeze.

MR. MAMMINGA: And that's very simple.

MR. LINK: I'm not real sure I understand it. But if we just put out an example and help me. And you're saying, okay, I've done my preshipment review, therefore I have produced the product.

But if I happen to have product that I put in the warehouse somewhere because a sample was pulled full of listeria and it comes up positive, have I then violated all systems, because I've actually shipped that product outside?

MS. FOREMAN: No. You haven't ship it.

MR. LINK: I did ship it. I shipped it to a warehouse. Is that --

MR. NEAL: A preshipment review is what it's called.

MR. LINK: Well, a preshipment review said I met my CCP's. That wasn't the last checkpoint for listeria.

MS. STOLFA: Well, I don't know if you want to complete your preshipment review before you have the results back. Some people don't.

MR. MAMMINGA: That is very correct.

MS. FOREMAN: Who?

MR. MAMMINGA: If you call it down upon yourself to listeria testing, you know, you do that because you want to, don't you? Well, I'm just saying that if -- we've had Iowa plants that have been, you know, had a positive listeria. And so then they go into, you know, they never ship a product that we test, never, because they want to have a recall.

MS. MURANO: Right.

MR. MAMMINGA: So then as a way of doing environmental and in-product testing to make sure they don't have the problem on going, again, they would be foolish to ship their own product until it has passed their own testing, because they are obligated. They are obligated to test.

MR. LINK: I understand. I think part of the problem, the reason this was even brought up was because we were shipping stuff off-site to another warehouse. And we were shipping product. It was in our house somewhere, but

we were getting in trouble because it was over there.

MS. STOLFA: Preshipment review is the demarcation point and has been since we first implemented this rule before product is produced. And we have been -- if you don't want to complete preshipment review until you get your test results back, you can make arrangements for that, even though the product is not still in your establishment.

MR. LINK: I guess I didn't know there was a loophole for all that. I just assumed when it went out the door, I had a problem with it. And that's the reason we were arguing this whole --

MR. MAMMINGA: From the very beginning --

MR. LINK: -- ship.

MR. MAMMINGA: -- even back in the old days when we were all pretty ignorant and I still probably am, if you had not -- if you hadn't completed preshipment review, you couldn't move it off-site.

MR. LINK: I didn't know that.

MR. MAMMINGA: Because -- but it's an understanding problem, not a regulatory problem.

MR. LINK: Isn't that, mark, why we were going at this?

MR. DOPP: Fundamental issue here was we've had a number of circumstances in which product was under the control, you know, at a company warehouse or some other

warehouse that basically is in the company's control, be it in a trailer or out the in the yard or whatever. I mean, I guess our point is if it's under the company's control, it shouldn't result in a problem.

MALE SPEAKER: Right.

MR. DOPP: I mean, that's the bottom line.

MS. STOLFA: Preshipment review is the demarcation point. And after that, product is produced and has been since the beginning of time.

MS. FOREMAN: But just let me ask --

MR. NEAL: But if it's in a truck until it's received by someone else, it is their property.

MS. MURANO: Right.

MS. STOLFA: We're not putting inspectors into making legal decisions. We are putting inspectors into saying to the establishment have you completed preshipment review under 417-5C. And if the answer is yes, the product has been produced.

MS. FOREMAN: But the company could ship that product to a warehouse and say to you, I have not completed my preshipment review. And it doesn't make any difference that it's gone on the truck and flew somewhere else.

MALE SPEAKER: Not numbers and everything?

MS. FOREMAN: Could not. It would still be under the company's control, because the company hasn't said to

the department I've completed my preshipment review under 417.

MR. MAMMINGA: And if the inspector came in and said, I saw for a fact the truckload of weenies sitting in the cooler and they are gone --

MS. FOREMAN: You can say --

MR. MAMMINGA: -- what happened to them? And you say, well, sir, see, here's my preshipment review. It's not complete. We moved it to Bill's warehouse 20 miles down the road. If you want to go down there and look at it, you can.

MS. FOREMAN: Right.

MS. MURANO: Right.

MR. NEAL: Would the paperwork --

MR. MAMMINGA: That would be acceptable. Some plants don't have enough cold storage space in-house to hold stuff pending their own in-house listeria sample. So you'd have to give them that flexibility.

MR. NEAL: Which has been part of the problem.

MS. FOREMAN: Incidentally --

MR. DOPP: I'm sorry.

MS. FOREMAN: Go ahead.

MR. DOPP: This was really written with sort of two thoughts in mind. And this is one and we've all had this circumstance. And I hear Pat saying that we can fix this is the way it was written produced or shipped.

See, and it was the oral language in there that presented a problem, because for example, if Charles' operation in the middle of the operation and they have a metal detector or they find something that is problematic, now obviously they have produced something even before they are shipping. We actually had that come up a number of times. Has that gone away largely through the interpretation or educating people?

MALE SPEAKER: Yes, it has, largely.

MR. MAMMINGA: I think if the agency rewrites it and explains it, as we have discussed it, I don't see where that ought to be a problem. I think it ought to be simpler. It gives plants the flexibility to -- that have limited cold storage space to move something.

For example, whether it's mandated or not, a lot of companies are doing their own listeria/salmonella testing and they sure don't want that stuff to actually change hands and go into commerce. But it gives them the flexibility to move it to point B where it can be safely stored while they are waiting for test results.

MALE SPEAKER: It's a function of simple storage space --

MS. FOREMAN: You know, I have had the occasion where I've had to try to explain to reporters that, yes, it physically got put on a truck and moved somewhere, but it

was still under the control of the company. And I think trying to straighten this out with something very specific, the company had not released it from its jurisdiction.

The department hadn't taken the final action to allow it out might be more understandable. This is, you know, for a lot of people when it's on that truck, man, it's been shipped. But at least it's a little easier. It's not --

MR. MAMMINGA: It's not produced until it's passed the preshipment review.

MR. NEAL: Yes. Our product does not go out. In our small plant, it doesn't go out until that's finished. You meet all the criteria and everything else, and it doesn't go until that's completed.

MS. MURANO: Well, if you'll notice on that first --

MR. HARRIS: And I think you similarly addressed it today. One of the areas that is still there for confusion under that scenario, then, is if you have product that has left the immediate premises and preshipment review has not been completed on it, then you run into the whole area of confusion over, okay, now which product is where that has that preshipment review and all that. Now that's a burden on both the plant and the agency. And did you indicate that there's going additional clarification issued

on that?

MS. STOLFA: We issue notice first, and then we can change the regulation to say our language will be produced and it will be tied to the completion of preshipment review, not to the physical location of the product.

MR. MAMMINGA: That's very important. That's the key to it right there.

MR. NEAL: It's still in the company's control if it's not preshipped, reviewed and signed, it's still our product.

MS. MURANO: Right.

MR. HARRIS: My only concern was the confusion over which product is which now once it's off-site.

MS. STOLFA: Well, you all have to deal with that.

MR. MAMMINGA: You have linings and codes and all that kind of stuff that's part of your preshipment review that identifies the stuff.

MS. MURANO: That's very doable.

MR. MAMMINGA: Okay. Can we look -- we only have a few minutes and they are going to make us quit. At the three questions at the bottom of two, what is the committee reaction to the agency thinking, I think we have specifically drawn those points out that we wanted to share with the agency about their thinking.

Now, there are two other points here on page three, "Are there additional factors or concerns that should be considered by the agency in developing its response to this petition?" Let's take a couple of minutes. If anyone has a suggestion here, let's take a look at it. I mean, they have responded almost line-by-line to the petition. What else?

MR. NEAL: Well, real quick without, you know, a big deal on it, just that it happens a lot in everybody -- and whether it's a petition or anything else. A lot of times most inspectors have trouble totally agreeing, especially when you get different inspectors.

And the other thing is they do things, and I understand you all are under such tight restrictions and things, they tend to be narrowly viewed, all situations. Anything on here and everything else, especially on this petition, they will look at things. And this is mentioned in this petition about looking too narrowly at things.

And I think that just goes with the territory with you all. I kind of almost am sympathetic with that. But it becomes a problem in plants, especially good plants. You're talking about the good plants, you kind of get offended.

I mean, here's someone with 137 NR's and you've got four, five. You know, and you're doing 10 times as much as they are. You know, so I think they tend to judge

narrowly. They don't take a broader scope and say, let's take a look here at what we've got here. It's a good plant.

MR. MAMMINGA: You know everything that they tried to do --

MR. NEAL: And that's what I have to say.

MR. MAMMINGA: -- from PDIS on, everything the agency has tried to do has tried to develop trend indicators that will sift out the bad apples. And it always, always, always comes down to the judgment of one or two, maybe three people, where you're going to pull the plug, because I'm the guy that pulls the plug. And I know what happens. And that is the part of this, if there is any art to it, that you almost can't teach.

MR. NEAL: Right.

MR. MAMMINGA: When Carol sat in charge of it, he had to make decisions. And they fell to her to live with them, good or evil, just like they fall to me or Pat or Charlie or any of us that deal in regulatory work. I appreciate your comments, but I don't know how we can teach that part of it. You know what I'm saying?

MS. FOREMAN: Yes.

MR. NEAL: That's all it was.

MS. FOREMAN: Ultimately, we find something other than demand and control inspection to running of the system. But we can't do that in the next 10 minutes.

MR. MAMMINGA: No, no. Are there any -- is there anything on that second bullet that we would like to offer up before we go look at the third one?

MR. LINK: Just one comment on the last piece, though, on the inadequate system part.

MR. MAMMINGA: Oh, very good.

MR. LINK: Just a comment real quick. I think if you define the produced-shipped thing the way we talked about, that may take care of a lot of problems, because a lot of it was -- and mark mentioned it awhile ago -- while we produced the product, therefore we had an inadequate system. And in essence, we don't. I mean, we found it, we caught it. Life is good. You know, and that's why I think a lot of that problem was --

MS. FOREMAN: Yes, yes. I hadn't thought about that. I feel really stupid. Thank you. That's -- I'm glad you noticed that. No. I was thinking about the physical presence of the thing, not because you found the listeria, your system hadn't worked.

MR. LINK: And I think that's the way it was interpreted before. If we produced it --

MS. STOLFA: And it's the opposite --

MR. MAMMINGA: Then it works. We had the toughest time getting the small plants to document corrective action, to document that they found a deficiency, because they

thought they were doing a bad thing. They were telling on themselves.

And I said well now, folks, look at it from the other way around. Does anyone expect that you would be perfect. And two, doesn't it show that you are doing the right thing in documenting that the system works.

MS. FOREMAN: Oh, boy, that makes those words even more important.

MR. MAMMINGA: Which ones?

MS. FOREMAN: The preproduction, the produced.

MR. MAMMINGA: Oh, yes. That's everything. That's everything. Okay. Let's look at the last bullet point. We've got seven minutes. Are there any -- well, are there additional areas of concern about which of the agencies develop guidance and instructional material to continue the success of HACCP limitation? And that kind of goes to the point you were making: Training, training, training. There is no substitute for training your people. I do it all the time.

MR. NEAL: Any materials that the agency gives us, too, needs to be as simple as possible.

MR. MAMMINGA: I would still --

MR. NEAL: I know you know that, but the simpler the better, because I think you probably will agree, I mean, you have employees that if it goes that far, that they need

to have it simple. Nothing personal. The easier it is, the happier they are. They are confused, they are not happy. I'm not very happy. I'm merely confused.

MR. LINK: Just one thing and I'm not sure if it fits in here or not, but just Charles Edwards was talking about it earlier today, but new technology, if there's a way to kind of get us some guidance on walking that through the system, that would be a big help. And I think he's working on that. But --

MS. STOLFA: Yes, Charles Edwards was here.

MR. MAMMINGA: That's really a good point, because he did touch on that for all plants, and considering where I come from for the small and the very small, if we can feed them proper, decent, workable, validated, new technology, it will just make them better. And why shouldn't we put some effort into that?

Before we buy our meat and poultry from 6 firms, not that they are -- or if we're going to have seven or eight, couldn't we help this to narrowly training? That's a very good point up there on question three, "Should we continue -- should we, as a subcommittee, encourage them to work on this new technology?"

MS. FOREMAN: I'd like to do that. And I want to say one more word about it. About 80 percent of the problems in inspection arise from just this thing we are

thinking about it's because so much in this system is subjective and so little is absolutely objective to the extent that we have technological advances that can say the litmus paper turned blue or it turned red. It passes or it fails. You would -- so the only way to buy ourselves out of that is to have the technology that removes this subjective decision-making, because humans are always --

MR. MAMMINGA: You've got five, haven't you?

MS. FOREMAN: No. You might have somebody say it was pink.

MS. MURANO: Purple, purple.

MALE SPEAKER: I agree with that.

MR. MAMMINGA: Let's see what's being written. I think this is a really good -- there you go, encourage, the big word, encourage, implore, beg, throw ourselves.

MR. LINK: And give some guidance, because I know trying to get this done -- and I think Alice mentioned it in the FDA symposium -- USDA, how do you get this done, the new technology? And, you know, I know that USDA is not necessarily approving that kind of stuff. But at least there's some --

MR. MAMMINGA: Well, Carol brought up a good point today. What happens to some of these discussions we had with ARS? Where did that go, you know? We haven't heard about that for a year.

MS. FOREMAN: There's a big pit over here in the middle of the Potomac. But if we can say that, in part, because it will reduce some subjectivity in decision-making, we've got to know why we want the new technology. It provides a higher level of protection, and it reduces subjectivity in decision-making.

MR. MAMMINGA: We've already got it written down. She's done a very excellent job picking up on our thoughts. Anything else? Or have we kind of chewed into it enough?

MS. FOREMAN: I want to go home, because my Coke's almost gone.

MR. MAMMINGA: I would thank all of you for your -- I thank you all for your very considered participation. It was a real good discussion.

MS. FOREMAN: Well, I learned a lot. Thank you.

MR. MAMMINGA: Okay. Thank you all.

(Whereupon, at 8:57 p.m., the meeting in the above-entitled matter was adjourned.)

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Docket No.

Washington, D.C.
Place of Hearing

June 5, 2001
Date of Hearing

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