UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

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NATIONAL ADVISORY COMMITTEE ON
MEAT AND POULTRY INSPECTION

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SUBCOMMITTEE NUMBER 1
MEASURING ESTABLISHMENT RISK CONTROL
FOR RISK-BASED INSPECTION

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May 23, 2006
2:30 p.m.

USDA South Building
Conference Room 0161
1400 Independence Avenue, S.W.
Washington, D.C.

FACILITATOR: MS. SANDRA ESKIN
Attorney
Public Policy Consultant

PARTICIPANTS:

DR. GLADYS BAYSE
DR. JAMES DENTON
MR. KEVIN ELFERING
MR. MICHAEL GOVRO
MR. MICHAEL KOWALCYK
MR. CHARLES LINK

ALSO PARTICIPATING:

MR. DONALD ANDERSON
MS. ALFREDA DENNIS
DR. CRAIG HENRY
DR. BARBARA MASTERS
MS. FELICIA NESTOR
MR. ROBERT TYNAN

I-N-D-E-X

P-R-O-C-E-E-D-I-N-G-S

(2:40 p.m.)

MS. ESKIN: Okay. So I'd like everybody, if we can start in this discussion by looking at page 2 of the PowerPoint handout at the top. On the first box, on the first screen, identified the six general categories of data that could be considered in this question of determining the effectiveness of this control.

If you start with number one, which would be the Food Safety System Implementation, we have listed under that identified by staff four general areas of -- four general points and some specifically defined data. I think that the real issue, which we will continue to discuss and which was brought up in the public meeting and public comments, is the question of NRs, noncompliance reports. That is one type of data that is currently collected by FSIS inspectors that may have some impact on this issue.

So the question I'm going to throw out to everybody is how do we want to characterize, address, limit, whatever, these NRs, this data. There's all

these NRs out there that have been identified already. Many of these reports have little or nothing to do with food safety. There's also concerns that it doesn't capture, these NRs don't capture all the food safety issues.

So I sort of have to be ready on the Subcommittee, NRs, are they relevant, all relevant, some relevant, what kind of action do we want to give the Agency on how to handle NRs in this -- how to use NRs in this context?

MR. LINK: Charles Link, Cargill. I'm looking at NRs, and not just within our company. I'm looking across the country and we have such an inconsistency with NRs being written. I mean you can go to one plant and get a couple a week and go to another plant and get 10 a week, and it's not -- there's no difference in the plant. It's just a difference in the application of how you want to write NRs. And I don't know if that's -- so I have a little bit of a problem with how NRs are going to be referenced because they're not the same across the country. There's a lot of NRs that are written as I

think has been mentioned that has zero to do with food safety and, you know, so we ought to weed those out and maybe, you know, as mentioned here, try to weigh or, you know, sort through which ones are more important than others. Maybe it's the old major/minor critical deal, the PDR days, I don't know, but you can't just take one at face value and say this is going to be measure. It just don't work. There's too many inconsistencies.

MS. ESKIN: You can't consider all NRs. That's the general point here.

MR. ELFERING: Kevin Elfering from Minnesota. As I had said earlier, NRs a lot of times are opinions and, you know, you're going to have maybe as many opinions as you're going to have inspectors.

I think that there might be some valuable information there but you'd almost have to first of all do a survey of NRs and really see what, what -- the food safety issues. NRs are written only for food safety concerns. We can make a review of them and get a much better feeling if they would be of any benefit or not. You know, you're going to have -- like

Charles said, you might go to a plant, who you have an inspector that just likes to write a NR, and then you might have a plant that has an inspector that doesn't like to write NRs, and may talk to them verbally. So it's too inconsistent.

Your microbiological data is going to be consistent.

MS. ESKIN: Right. Okay. So one thing Kevin just suggested and let's think about this is, going back to the Agency and saying you need to do -- you should do, we think you should do, some sort of comprehensive review of the whole NR system and see what changes might be made to allow the easier capture and the more consistent capture of food safety related NRs.

UNIDENTIFIED SPEAKER: Before considering in this risk-based assessment.

UNIDENTIFIED SPEAKER: Yeah, do the assessment of the NRs.

UNIDENTIFIED SPEAKER: And then if you find really good consistent data, then definitely. Then you --

UNIDENTIFIED SPEAKER: You can justify including them.

MS. ESKIN: Any comments from the Committee members on that issue? Gladys?

DR. BAYSE: Gladys Bayse. I -- that sort of process down for what we're trying to do. It sounds like it needs to be done, but should that be an initial -- I don't know.

MS. ESKIN: I think that's a concern to raise but this is a potentially -- I mean this is data that's currently collected. It's part of the process and it could be useful in this -- I understand and appreciate the concern about not wanting to slow it down, but we want to do it right and doing it right may mean it takes a little more time than we'd like it to take.

DR. DENTON: I think in following up with what Sandra's saying, we have a lot of information, and we're really not sure what the quality and usefulness is, and before we recommend making a change in that, I think we probably need to mind that data set just a little bit to see if there are some useful

things there that would guide us in our thinking with regard to what perhaps could be modified in that.

MR. ESKIN: Mike, did you want to say something?

MR. KOWALCYK: Yeah, this is Michael Kowalcyk with Safe Tables Our Priority. To follow up on that point, and I think Charles brought up a good point, that even within an organization, there's differences, and I mean even just rudimentary measures, on average, I mean we're looking at 5500 plants that we're looking at here. On an average, in a month, what's the average number of NRs any given plant could expect to have, and what are those NRs like. What makes up those NRs because if we're going to use this to drive some type of data driven process, the metrics need to be consistent, and I don't know if USDA has historical data, how far back it goes, where you could go back and look at NRs over a period of time to get a sense for, you know, probably cut off, you know, post-HACCP because pre-HACCP probably doesn't apply. And, you know, take a survey to see, you know, how many are there out there and maybe

categorize them as to certain categories. So taking that step back because my concern would be doing -- following up something where you would incorporate NRs and then try to apply some type of weighting. You might not have the most accurate picture, and I mean just this question, how do you make a recommendation when you're really not sure what you're dealing with.

MS. ESKIN: You can at the very least make this initial cut perhaps, meaning is it food safety related. I know it's not a black and white line.

The harder perhaps step, is the next one which is between -- among this universe of food safety related, does some get more weight than others, but at least initially because in my mind I think we're comfortable --

MR. LINK: We can do that pretty quick, but you couldn't do it just saying, well, you know, one plant has more numbers of food safety NRs because that varies by region of the country.

MS. ESKIN: Right.

MR. LINK: I think, Mike, the comment you made on the consistency, if you look district to

district, it's consistent year to year if you look at NRs that are written, you know, in some general area of the country that they write all the NRs. In other areas they don't.

MS. ESKIN: Right.

MR. LINK: Then you get plant specific stuff, too, that's different.

MR. TYNAN: Could I interrupt for a moment before you move onto your next topic? This is Toni Law (ph.). Tony is one of our Administrative Assistants, and she's coming here to help us and as you get ready to do the report, she'll be able to do that.

MS. ESKIN: Great. And I've been taking lots of notes. So --

MR. TYNAN: Whenever you want her to start typing, she's ready.

MS. ESKIN: Okay. Great. One other thing about, you just mentioned with this NR review. It would obviously be done, supervise with FSIS staff but also getting the inspectors involved since they're the ones who issues these NRs who are actually in the

plant that would be essential.

Mike, did you want to say something?

MR. GOVRO: I have a couple of points. At the State level, we've always used a ranking system for violations, and these are often used in coming up with a point total for a food service establishment in order to give them a ranking like A, B, C or in compliance, out of compliance, various systems used around the country. So a lot of work has been done in, in weighting which I think could be accessed. And recently we've had critical and non-critical -- food code brought in the CDC risk factors which are like extra critical violations and, you know, I think it would be important to rank them if you're going to use them.

Having said that, I talked earlier about using data on violations to compare one inspector to another, and found that there was such a variation between inspectors on our staff, that I found the data to be useless, and the instance we had the opportunity to go away from using those scores to communicate to the public, we did it. We got away from it because I

just had no confidence that there was any consistent message that could be delivered. So, you know, if you look at how things are marked from one part of the country or one plant to the next, and you find, you know, I would find that I would have some people marking a certain violation 0 percent of the time, and another person marking it 70 percent of the time. Something's wrong there.

MS. ESKIN: So then how do you fix that?

MR. GOVRO: Well, it's a training issue, and you can close the gap but, you know, and these types of things as Kevin said, it's an opinion and that's very subjective data, and I really question the value of using something like that to come up with a quantified score that puts somebody in a particular category. I'm uncomfortable with that.

MS. ESKIN: Are you comfortable with at least this level of suggestion meaning taking a look the NRs, try to get some sort of a comprehensive assessment of how they currently are used, what does have a food safety implication or do you think that's not going to be a worthwhile exercise?

MR. GOVRO: No, I think they should be looked at in a way and weighted or ranked in some way so that you can decide which ones you want to use in an assessment, but I think you need to have a pretty high level of confidence that you're not getting opinions and that you've got one guy that, you know, as someone said, just doesn't like to write NRs, maybe they're too much trouble to do, and another guy that just, you know, he's got it in for somebody and he likes to write a lot of them.

MS. ESKIN: So be aware of these issues of inconsistent application --

MR. GOVRO: Yes.

MS. ESKIN: -- and -- right. Okay. Are there any other comments first of all from the Committee members on this issue regarding NRs?

MR. LINK: Just one other comment. Charles Link. Somebody mentioned the failure. They do try, currently try, number of tasks performed, number of tasks actually failed, whether -- which would result in a NR which might I guess you could write it down. That might be something another 11 would look at in

examining how much of a failure rate is a plant particularly running on a particular task.

MS. ESKIN: That data's collected but is it -- you're saying it's currently --

MR. LINK: USDA has it.

MS. ESKIN: USDA has it but they don't necessarily do anything with it right now.

UNIDENTIFIED SPEAKER: We analyze it.

MR. LINK: Really.

UNIDENTIFIED SPEAKER: Yeah.

MS. ESKIN: All right.

MR. ELFERING: One other thing, too. Kevin Elfering. You have HACCP failures. You have SSOP failures, and should risk-based inspection be based on a facility that is operating in unsanitary conditions.

MS. ESKIN: You're saying it's not.

MR. ELFERING: Maybe that should be a consideration. If you have, if you have a lot of SSOP failures in a facility, that should also be considered in whether or not that facility may be at a higher risk for producing a -- product.

MS. ESKIN: How is that SSOP failure

recorded? In other words, how does the --

MR. ELFERING: It would be on the NR as well.

MS. ESKIN: Right. Right. That's what I'm saying.

MR. ELFERING: I mean you want to be able to --

MS. ESKIN: That would capture it.

MR. ELFERING: You want HACCP data, HACCP failures, and SSOP failures.

MS. ESKIN: That goes back to this ranking question but like it's been said, once it's been figured out where they all sort of fall.

MR. ELFERING: But then again you have to sort out that you don't want to have record -- not necessarily recordkeeping failures but actually equipment that has not been cleaned properly, where you actually are doing -- when they're doing verification, and the inspector is finding that equipment wasn't cleaned properly, not record failure --

MS. ESKIN: Right.

DR. DENTON: Right. Not clerical, but the actual --

MS. ESKIN: Any other comments on NRs?

MS. NESTOR: The HACCP failures are 03, right, and the SSOP failures are 01, but as I recall when we got the BSE NRs, you know, sometimes you have some food safety problems that slip into 06DO1.

MS. ESKIN: Which is what?

MS. NESTOR: Which is facilities but you get some food safety, so I don't know how -- I mean there are hundreds of thousands of NRs. I don't know how you're going to separate these things, you know, I don't know whether it's just going to be so easy as to just say, okay, we're just going to take the 03 safety ones.

MS. ESKIN: Well, it seems like a reasonable place to start. It may result after doing some sort of comprehensive review that it may be too problematic to set up a system, and something else may need to be created that would reflect it. I don't know. I'm just saying do you think it's still a reasonable, still a worthwhile endeavor to take a look at, in some

systematic way, NRs, for this reason, to kind of get a sense of how to measure?

MS. NESTOR: Do you mean all NRs or do you mean just looking at the 03s?

MS. ESKIN: Well, you have to -- I think that looking at all NRs initially.

MS. NESTOR: Yeah.

MS. ESKIN: Just because they're categorized a certain way right now doesn't necessarily mean they do or don't have food safety implications.

MS. NESTOR: I think it's worth looking at but I really hear what everybody's saying, the sources of inconsistency.

MS. NESTOR: Okay.

DR. DENTON: I have a question?

MS. ESKIN: Yes.

DR. DENTON: This is James Denton. I'd like to ask Barb, you know more about the data probably than anybody sitting at the table because you've seen what's been accumulated. Is it reasonable to expect that you can assess that across the NRs and develop those into categories?

DR. MASTERS: I'll make a couple of comments, and actually Alfreda also has a comment.

Since we've began implementing HACCP, all NRs have a block on there for food safety versus non-food safety. So I think you could analyze the data and break it out into food safety versus non-food safety.

I think the bigger challenges come into play which is what you're starting to get into asking the questions is how do you define once you start looking at the safety NRs, which of those are the food safety NRs of concern which is what we really I think are trying to get some input on from this Subcommittee.

More importantly, getting to the point that Felicia is going to raise is in December, the Agency put into place some pull down menus, some drop down menus for our inspection personnel trying to get some consistency for our data analysts, and that is related to O60O1 is actually our sanitation performance standard code, and so that area as well as within our HACCP procedure and our FSIS procedure codes, we have drop down menus that try to break down recordkeeping

versus monitoring versus verification, to allow us the opportunity to do a little better drilling down in our data analysis. We just implemented that in December. It would be nice to have that to go a little more retrospectively but that's allow us to do better analysis of our data. So that was something that came into play much more recently for the Agency that is allowing us to do a lot better, to look at the records, peer recordkeeping versus the actual, you know, failure of sanitation.

MS. ESKIN: Uh-huh.

MS. DENNIS: I'm Alfreda Dennis. I'm an inspector. I hear the concerns and comments about the opinion of the inspector which sometimes you can't look at, but if you have -- when a NR document describes a violation of regulation and you cite the proper regulation and the incident and describe it as it happens, if there was a food safety incident or even an SSOP or a consumer protection, if that NR can stand up to, you know, field process and they are valid and it will -- it should be able to be put in a category where it will show a history.

Now there might be some people where some plant management don't feel that this is an opinion but when you look at what happened and describe it and it's weighed against the regulatory violations, then they can always put them down. You can take a -- and you may start out not directing affecting a product and if you watch that situation and then you follow it, but there's no problem involved at that point. Last week we had that problem with a piece of equipment. Next week, the same problem exists but -- so that situation can relate into a direct product contact situation. So the inspector that's documenting it properly can show the connection between the non-product contact violation versus the actual contact using the 03 or 01B or C or whatever it is. They can -- and it can be a valid point.

So, yes, you could start by looking at the data of the NRs, how they're going to stand up and are supported by the violation. I think it would be a valuable source of information.

MS. ESKIN: Okay. Let's go onto the second point, and again I'm sure our discussion will come

back to some of the issues again when we look at the other two questions.

So the second component is identified as food safety system design, and it does highlight the food safety assessments that are done.

I had a question and, Barbara, you can answer this one for me. How often are these done? Are they done with any regularity? Is every establishment one done every year, less than a year, more than a year?

DR. MASTERS: Our goal is to do a food safety assessment in all of our establishments. Obviously it takes a more significant amount of time to get into all establishments. So right now they're done for cause.

MS. ESKIN: Okay.

DR. MASTERS: They're done when we implement a new procedure. Right now we're doing them. For example, in our high risk establishments for listeria, as we're risk-based listeria verification, and then we do them randomly across establishments and obviously those are our lowest priority, and then we're doing

them in our salmonella -- risk-based salmonella initiative that were put out in February. We're doing a safety assessment on a risk base. So establishments are not meeting our performance criteria on salmonella, they will be a higher priority for getting food safety assessments. So they're kind of prioritized as to how they come in.

Right now I think we're about every three years is what we determined. Is that right, Don? Is that what we've looked at?

MR. ANDERSON: Yes.

DR. MASTERS: The entire 5500 plants will be getting a food safety assessment.

MR. ANDERSON: Probably the average time since the last one, maybe a little shorter because we had sort of this -- push but I think it would be safe to say that generally it's at least a year, a couple of years.

MS. ESKIN: And again, in general terms, this assessment looks at --

DR. MASTERS: The design of everything.

MS. ESKIN: -- the design of everything, not

necessarily the implementation of everything.

DR. MASTERS: The in-plant inspection personnel like Alfreda look at the execution on a day-to-day basis, and the design, they look at everything. They're trained. Our EIAO officers are trained to look at the interrelationship between the sanitation parts, SSOP and HACCP and how they relate together.

MS. ESKIN: Kevin?

MR. ELFERING: Kevin Elfering. One thing that I think we really need to look at is what is a food safety issue. I mean you're going to get a lot of disagreement perhaps, but to me BSE is not a food safety issue.

MS. ESKIN: Okay.

MR. ELFERING: So first of all, before you starting doing an assessment, you have to identify what the food safety concerns are.

MS. ESKIN: In particular. You're saying generically just identify them.

MR. ELFERING: You need to be able to identify them. Certainly listeria or salmonella in a fully cooked ready-to-eat product is, is a significant

food safety issues. Not removing spinal cords from cattle that are over 30 months of age to me is not a food safety issue. It's certainly going to be a trade issue --

MS. ESKIN: Uh-huh.

MR. ELFERING: -- with being be exported and it's been shown that it is, but really it is not a significant food safety issue.

MS. ESKIN: Shouldn't that identification of what is an issue, I mean again be reflected in the HACCP plan and the other design elements, either aspects of the design of the particular plant?

MR. ELFERING: It's not our duty to reflect them. Again, you're going to get different opinions on BSE. They have to address it in their HACCP plan.

MS. ESKIN: I wasn't asking about BSE specifically. I was asking it more generally.

MR. ELFERING: But you still have to address BSE in your HACCP plan.

MS. ESKIN: Right. Uh-huh.

MR. ELFERING: But really is it a public health issue? No, it isn't. But it still has to be

addressed in the HACCP plan.

MS. ESKIN: Any other comments?

MS. DENNIS: If you say no, then all you need to do is justify why it's not.

MR. ELFERING: Oh, definitely. Right, you still have to do it in the hazard analysis and you have to identify it. If you were slaughtering all cattle under 30 months of age, that's not an issue.

MS. DENNIS: Right, because you can document why.

MR. ELFERING: But then you saw -- but then you still have to, if you're a slaughter plant, you still have to deal with the SRMs that are associated with cattle less than 30 months of age. So really can you ever say that it's not a hazard reasonably likely to occur and not include it in your HACCP plan?

MS. DENNIS: It depends on --

MR. ELFERING: Only if you're -- maybe if you're slaughtering swine.

MS. ESKIN: Does the group of Subcommittee members agree that this particular component, that is to say, consideration of a food safety system design

is relevant to a determination of the effectiveness of risk control? Does anybody think it's not?

UNIDENTIFIED SPEAKER: Do I think it's not?

MS. ESKIN: Does anybody think it's not? Does anybody want to add any other specific details?

MR. LINK: I think it's important but --

MS. ESKIN: Uh-huh.

MR. LINK: -- I'm not sure you can, we were just talking, the FSA is maybe once every three years somebody might come around, I mean if it's not done for cause, I guess. But even then you can debate because you still get down to the opinion of I think you designed it improperly and I think I designed it properly --

MS. ESKIN: Uh-huh.

MR. LINK: -- and it's working for me. So it's still kind of a subjective area. When we do our own assessments, you know, everybody does an annual HACCP assessment. You have to do those. We have a third party obviously come through that you can't even count on all your hands and fingers but, you know, all of that stuff is sort of held confidential because we

don't want it, you know, spread all over the newspapers. Just very little inadequacy that somebody might point out in the plant, but I mean there's a lot of ways that food systems are evaluated.

MS. ESKIN: Uh-huh.

MR. LINK: I mean the food safety assessment that FSIS is doing is so -- not, not --

MS. ESKIN: Not good enough.

MR. LINK: I'm not getting for more. Please don't misunderstand me.

DR. MASTERS: Let's see. Next week --

MS. ESKIN: We answered the easier question perhaps.

MR. LINK: That was James Denton.

MS. ESKIN: So it still should be considered but as far as to ranking it, we'll get to that later. It's not necessarily as high as other factors or components.

DR. HENRY: I have a question if I may, Madam Chairperson?

MS. ESKIN: Yes.

DR. HENRY: How do you evaluate, how do you

rank, how do you say the food safety system is good or bad?

MS. ESKIN: Anybody want to respond to that?

DR. HENRY: We've had a lot of discussion about NRs going into it.

MS. ESKIN: Right.

DR. HENRY: FSAs going into it. How do you define today, how do you say whether an establishment has been effective in producing some product?

MS. ESKIN: How would you define it?

DR. HENRY: Well, it's face value issues and NRs, if you look at most plants, especially the slaughter room, they typically average anywhere from 200 to 600 NRs per year. It's a very complex system but if you look at recalls, major CCP and repeated failures, obvious -- associated with attributable data. They get some pretty good bench warrants on them. So looking at that and trying to say how do you gear up to say whether one plant because there's certain -- that's been looked at by industry and by FSIS. If you look at the NR, you'll find plants out there that virtually no NRs are issued and it had

significant recalls.

MS. ESKIN: Uh-huh.

DR. HENRY: And where food-borne illness was associated with it. So you're kind of splitting hairs and I think you'll find there's a huge amount of variability in the NRs.

MS. ESKIN: So you're suggesting that the value of the NRs may be limited in this context?

DR. HENRY: No, I want to forget about the NR. I'm just saying, you know, what do you say? What isn't in here, a good or bad system, saying to your point on the table --

MS. ESKIN: Right.

DR. HENRY: -- which is what is an -- food safety system. Is it a FSA audit? I would submit that a good food safety system is a plant that has a consistent, proven record of no recalls, no consistent CCP failures, no food-borne illness related to it. I mean those are the real -- that's what --

MS. ESKIN: When you say history, how long of a period are you suggesting?

DR. HENRY: There's date out there for one,

two, three years. But I mean you're going to go back and look and evaluate the system because a FSA evaluation is no different than a NR because in both cases, it's opinion driven.

MS. ESKIN: Uh-huh.

DR. HENRY: And if Barb can only do one and I can only do one, we may both see it differently if James Denton did one. We all have a little different table of support. So I think it's important to consider that.

MS. ESKIN: Right.

MS. NESTOR: Yeah, I think recalls are a very bad way of determining whether a plant is -- yeah, if you can trace a recall back to a plant, yeah, they have a problem, but absence of evidence is not absence of efforts. I mean there are a number of reasons why some of the large plants haven't been identified because FSIS just has not done trace back. They tested at the end of the line and the original plant, the slaughter plant was never traced back to. So just because that plant was never identified but the process is designed so that plant is not

identified.

MS. ESKIN: Kevin?

MR. ELFERING: Kevin Elfering. I think in some of the past discussions we've had, we've talked about numbers of different types of data. For example, FSIS collects salmonella performance standards, and I believe all of that is PFGE. So you have Public Health Departments are investigating food-borne illness outbreaks. They're doing -- well, most of them are doing PFGE on those outbreaks.

You've been doing salmonella and listeria sampling of full cooked ready-to-eat product. Again, you can kind of correlate that with, with public health outbreaks.

You know, if you have a very small client that only has intrastate commerce and you pick up a certain PFTE pattern, listeria in their plant, and you have an outbreak in the State, you've got pretty much the proverbial smoking gun which would be included in data like this. So I think it's not just NRs and food safety assessments. It's a lot of data that we're ready to discuss as trying to make a basis for this

risk-based inspection. So those have all been considered as well.

MS. ESKIN: Uh-huh. Any other comments?

MR. KOWALCYK: This is Michael Kowalcyk. I think to follow Kevin's point, and the discussion we had about NRs and FSAs where subjectivity comes into it. It just seems like it's the nature of what those are. And when you get so far as to outbreak data and recalls from the consumer side, that's too late. I mean people are getting sick.

So is it a question of looking at the sampling and taking more of a quality control approach as the Agency would step up its sampling during multiple points in the process to see if those controls are working because that is an objective measure. And reevaluating how the samples are done. I mean there are instances they can point to where a random sample was really taken but was given notice a day or two prior to the sample being taken. Well, then, you know, and the work I do in direct marketing, when we take random samples and you certainly -- you want to be blind to that stuff. It has to be truly

random. So it's, so it's what's going on day-to-day. So I don't know if that's within the realm of this, if you're collecting data that's objective, that should probably be looked at.

MS. ESKIN: Uh-huh.

MR. GOVRO: Question for FSIS for anybody who knows the answer. There's been a lot of discussion about recording NRs and how many the firm gets and of what type and so forth, and, and it strikes me that that is a recording of a negative situation, and I'm wondering if each day the inspectors do an actual inspection, where they run the whole checklist and mark whether things are in or out, good or bad.

For instance, when we do an inspection, rather than simply write violations particularly with the CDC risk factors, we'll mark one of four categories, in compliance, out of compliance, not observed or not applicable, and that gives us a better picture of the actual compliance level that's there on that particular day and if you have a system where you're only recording NRs, you may not get as clear a

picture of how the plant operates as if they had a complete inspection record each day. So do they do that or just --

DR. MASTERS: Yeah, this is Barb Masters. Under our current system, it's a performance based inspection system and our inspection personnel are provided inspection procedures that they go in and perform, and they document it as performed in compliance or performed and not in compliance and then they would document that NR and what procedure code was in noncompliance but they do perform -- document those that are in compliance. They also have the flexibility of performing non-scheduled procedures if they see something that they believe is important to follow up on or if they see something that was out of compliance that they need to document. So they can do non-scheduled procedures in compliance and non-scheduled procedures that are out of compliance. So they do document both compliance and noncompliance in those cases.

MR. GOVRO: So when we have this discussion of the food safety system implementation in the food

safety system design in bulk, I think it could be addressed by a look at that larger set of data rather than just NRs. And I don't know if that's what you considered or not, but that would be the way I'd go with it.

MS. ESKIN: You mean there's more data beyond those two general categories that FSIS has that would be relevant. Is that what you're suggesting?

MR. GOVRO: Well, it's sort of an answer to Craig's question about how do you determine whether a food safety system is designed properly. I think you could -- I think there's more than just NRs that can address that or the food safety assessment.

MS. ESKIN: Go ahead, James.

DR. DENTON: James Denton. I've been thinking about this and listening to the discussion. I think I need to go back to what Craig said a few minutes ago.

As we look at those things that we have oversight and control over, the NRs, the sanitation violations, the critical control point violations and then the food safety assessment and then anything that

gets into commerce that results in a food-borne illness outbreak, I agree with Mike. It's a little too late, but that is the end result of the accumulation of all these other things that have gone before it. So that still comes back to the most serious assessment that we have in which we've had a system failure because the system didn't catch it before it got into commerce.

Now the recall is the next best thing to that because at least you didn't make anybody sick if you can get the recall before you have a food-borne illness in place. You realize you've had a CCP failure and you can pull the product back before you have a food-borne illness outbreak. Neither one of them are good. Don't misunderstand me. What I'm saying is one is the worst case and the one is the next worst case that you have, but taking these things altogether, I think that we have to look at all of the data where we can actually get hard numbers with regard to recalls and with regard to food-borne illness outbreaks because this whole thing still comes back to the issue of protecting the public health and

when we have a failure in the system that results in failure to protect the public health, that's the worst violation --

MS. ESKIN: Uh-huh.

DR. DENTON: -- in the whole picture. And looking at how we sort out the NRs that are not critical factors from the food safety standpoint, that's going to take some time obviously to mind the data to give us some indication there but I think we have to look at every single piece of really good valuable information that we have in making the determination on the second one of whether or not we have a good food safety system design.

MS. ESKIN: Right. Right. Let's move forward to the pathogen control on the top of page 3. We've got all of the data that FSIS has collected through it's own testing programs and again the threshold question for our purposes is, is this data relevant to the question of the effectiveness of an establishment risk control measure? Should this data be considered or perhaps not considered? Kevin?

MR. ELFERING: I mean this is some of the

most important data that you have.

MS. ESKIN: Okay.

MR. ELFERING: The salmonella performance standards, when you, when you have a client that is still meeting the salmonella performance standards but marginally meeting the salmonella performance standards as opposed to one that is by far achieving way below, I think that that's important data. So it shouldn't even be pass/fail in cases like that.

DR. MASTERS: If you look at the chart, and I'm sorry, Madam Chair, in our actual paper, that is what you'll see is reflected in our chart, our current CD from our February paper that we had proposed to the committee is consistent, variable and poor control which was consistent with our thinking in February of the plants that are at the standard, at less than half a standard. And so that is kind of what our thinking was.

MR. ANDERSON: In fact, those several measures also look at the presence of sera types that are known, human sera types and that's not only looking at the prior ones, salmonella but also --

MS. ESKIN: So besides registering our view as a Subcommittee that this is some of the most important data that FSIS collects, do you want to give any other direction, any other comments that may be worthwhile to them?

MR. KOWALCYK: This is Michael Kowalcyk again. I think -- I would agree with Kevin wholeheartedly that this is critical data, and I guess in the way that samples are taken, the Agency should be sensitive to getting a fair representation of large plants, small and very small plants across the country because you want, you want to have a really robust data set here to use. So I think that's something that will be very important.

MS. ESKIN: There's a wide range of establishments.

MR. KOWALCYK: Yeah, the sampling methods are sound and validated.

MS. ESKIN: Any other comments on this particular component?

MS. NESTOR: Seasonally, do you have to take that into account?

MR. KOWALCYK: That would be part of it. Yeah, it would be throughout the year. Obviously we wouldn't take them at one point in time.

MS. ESKIN: Okay. Moving forward, looking at the fourth component, that was identified --

MR. ELFERING: Madam Chairman, if we can go back. One of the things that we have to look at again, with pathogen control, is you have to identify the type of an operation as well. You know, if you have a plant that is only bringing in source ingredients and grinding and you have positive E. coli O157:H7, is that something that occurred at the grinding facility or is that something that occurred at the slaughter facility?

MS. ESKIN: Right.

MR. ELFERING: And I think that's another thing that has to be taken into consideration.

MS. ESKIN: I know it's been brought up, and I've made a note here. It's not simply a wide variety of size, but also the type of operation.

MR. ELFERING: Type of operation. You really have to look at -- you really want to try to

identify where the source of contamination is. So if you have a grinding plant, your source of contamination is very likely the slaughter plant. Well, then maybe it needs to be -- maybe the trace back has to go further before you can include that data in that grinding plant's --

MS. ESKIN: Risk control --

MR. ELFERING: Yeah.

MS. ESKIN: -- assessment or whatever. Uh-huh. Any other comments on this issue?

Let's look at number 4 which is given the heading, in-commerce findings, and again what's listed here are consumer complaints, recalls and other considerations. Any comments on let's say the first two or let's start with the first one. Consumer complaints. Is that relevant data?

MR. GOVRO: A little bit.

MS. ESKIN: A little bit.

MR. GOVRO: A little bit. I don't think it's a very comprehensive collection of problems that people think. I think most people don't complain about a product that's spoiled too quickly or whatever

they --

MS. ESKIN: Right.

MR. GOVRO: It doesn't get back to the USDA.

MS. ESKIN: So it's relevant but not as relevant as other data or important I should say.

MR. GOVRO: And in consumer complaints, are we also referring to food-borne illness reports that -- it includes that. Okay.

MS. ESKIN: And again, those are the food safety related complaints. I assume these the ones that you've been capturing.

MR. ANDERSON: Consumer complaints go through a fairly rigorous process within the agency to see if they're valid, they're viable, kind -- I don't know the terminology that's used, but there's a process that's fairly rigorous, and it gets in some sense judged or determined at the end process of, yes, this is a real public health complaint that is traceable back in particular to somebody or not.

MR. GOVRO: Right.

MR. ANDERSON: And we would certainly, you know, take that into consideration I would imagine.

MS. ESKIN: Right. Yes, James?

DR. DENTON: Is there a distinction made between the complaint with regard to a shelf life issue as opposed to a food safety illness outbreak?

MR. ANDERSON: Absolutely.

DR. DENTON: I think a food safety -- perhaps would be more, more appropriate, that the food-borne illness category be separated even within the consumer complaint category?

MR. ANDERSON: They are.

DR. DENTON: They are. Okay.

MR. ANDERSON: Yes.

DR. DENTON: Because one is a quality issue and the other one is --

MS. ESKIN: Right.

MR. ELFERING: Another question on that, foreign material complaints, are they also looked at and do they have a significant --

MR. ANDERSON: They are looked at. As I understand it, not all -- I mean all foreign material problems are an issue to the Agency but some will be considered actual physical safety hazards, metal or

glass --

MS. ESKIN: Right.

MR. ANDERSON: -- are going to be definitely considered food safety issues.

MS. ESKIN: How about undeclared allergens. Is that considered a food safety issue?

MR. ANDERSON: I know under the recall process I know that they are. I believe allergens, undeclared allergens are considered Class 2 public health recall. So the answer to that in a consumer complaint would be, yes, as well, they'd have to check on that.

MS. ESKIN: So again, under this category so far we've just discussed consumer complaints, the consensus is they're relevant, not as important as other data but certainly those that clearly go to food safety and particularly food-borne illness incident are important to this assessment consideration.

UNIDENTIFIED SPEAKER: The in-commerce issue.

MS. ESKIN: Right. And, okay. Recalls, the more serious, the two most serious classes of recalls.

MR. GOVRO: I have a question. What percentage of your recalls are recalled product? I don't know how you might quantify it comes from product that was tested and shipped rather than tested and held? Is it a large percentage?

DR. MASTERS: It's in that --

MR. ANDERSON: As far as -- there were only about -- I say only, you know, any is too many, but there were approximately 40 recalls last year, and I'm pretty sure that probably 80 or 90 percent of those were as a result of testing, positive test results mostly I think for listeria.

MR. GOVRO: Okay.

MR. ANDERSON: So to answer your question, that product was -- most product shipments are being held when they're tested but --

MS. ESKIN: But not all of them. Eighty percent of the recalls involve product that was not --

DR. DENTON: Twenty percent that were tested cleared and then turned up positive in a recall.

DR. MASTERS: The majority of our recalls last year were for -- we had several that were for

undeclared allergens.

MR. ANDERSON: We have a variety but there were some for listeria. There were some for undeclared allergens and, of course, some recalls are an issue because companies themselves identify problems that the product got shipped. Maybe we didn't even test it but they identified a problem that was in a product they shipped and, of course, all recalls are voluntary but kind of initiate that themselves based on their own findings, their own test results.

MR. GOVRO: Well, what I'm getting at with my question is that if you take out the recalls that were initiated from sample results which we've already addressed sample results in another category. We're not talking about a lot of recalls. Ten, fifteen.

MR. ANDERSON: In which category?

MR. GOVRO: Not related to sampling results.

MR. ANDERSON: I would think it's probably 10 or 15. That's easily checked.

MS. ESKIN: Your point is that it doesn't necessarily give us a lot of data.

UNIDENTIFIED SPEAKER: It's not a big set of data.

DR. MASTERS: It's not a big set of data but they are typically still Class 1 or Class 3 recalls and for those establishments that have them, it is still relevant.

MR. ANDERSON: Right.

MR. LINK: The other question is, too, is if you had a recall like two years ago, wouldn't you --

DR. MASTERS: For you? Did you want us to take the assessments --

MS. ESKIN: I still think that's, you know, history of whatever.

MR. LINK: At some point, you know, maybe you've learned from that and you've dramatically improved your food safety system, but you only get credit for that because it still shows up three years later or whatever.

DR. MASTERS: But you haven't had any subsequent violations.

MR. LINK: Well, no. I'm just asking questions. You use it as criteria, at some point

you've got to roll it out and let it.

MR. ANDERSON: That is a valid question for all of these data, how far back do you go, and something we are considering. We are thinking about that.

DR. MASTERS: Yes.

MR. KOWALCYK: One other thing to follow up on that, even in the case where a company will initiate the recall if they find something in their own quality systems and they want to pull the product back, it might be out of the scope of this question but what is the -- basically the post process that the Agency and organization would go through after a case like that? Obviously they want to make sure that as much product comes back as they can get but then after that, should there be -- if you want to incorporate this data into Charles' point, then if the company has a recall and they corrected the problem, and hopefully the event of that happening again would be lowered by their corrections. Is there some type of mechanism in place where the Agency would evaluate their processes, what they found to correct, and maybe a food safety

assessment but is there a process in place or should there be a process in place to feed into something like that? The company recall, took these interventions and --

UNIDENTIFIED SPEAKER: They did a good job.

MR. KOWALCYK: Yeah.

MR. ANDERSON: Well, I think it's true, as Dr. Masters said, that a good number of the food safety assessment are scheduled for cause or are scheduled as a result of that kind of an -- finding, and as I said, there are overlaps in these areas, you know, a positive listeria finding or E. coli finding may also result in a recall if the product wasn't held which may also involve consumer complaints, you know, and is likely to trigger a food safety assessment which would then also be part of the process that you're talking about and usually follows up with corrective action which we have to look at.

MS. ESKIN: But Mike's point, I think, was does that -- does the company's subsequent response to this problem, is that registered anywhere.

DR. MASTERS: And it may help, where it fits

in here, the company has to develop then a verification plan and then individuals like Alfreda would then have a verification plan that they use then their inspection procedures to look at that verification plant to insure that the establishment is following up with their verification plan.

MS. ESKIN: Is that part of the food safety system?

DR. MASTERS: Yes, it would.

MS. ESKIN: Okay. That makes sense.

MR. ANDERSON: It is, and indeed the most serious finding I guess you could say of a food safety assessment is a notice to the establishment that the inspection is going to be withdrawn and then the company typically responds with corrective actions or a corrective action plan which the Agency then evaluates.

MS. ESKIN: Kevin.

MR. ELFERING: I apologize if this has been hashed over before but we should also be considering those companies that hold product, don't ship it and get positive results and let's say we had a company

that held product and they had it 10 times during the year, they had positive samples but luckily they held it and it's not associated with a recall, but they're a much higher risk, if they had a considerable number of positive results.

MS. ESKIN: Wouldn't that be, you know, better than you're saying letting it go in commerce?

MR. ELFERING: Yes, from looking at that facility and saying this is a much higher risk facility than this one over here. Really if they had 10 positive samples and never shipped anything and didn't have a recall, I mean this one had one positive and this one shipped, and this one, this is a higher risk facility because they had more positives even if they didn't ship.

MS. ESKIN: Are you saying that it's better that they didn't ship?

MR. ELFERING: No, I'd say that they have a very significant failure in their system.

MS. ESKIN: Is there anywhere that that's reflected.

DR. MASTERS: I hear Kevin saying that maybe

it should be weighted higher for having more positives.

MS. ESKIN: Ultimately, since that's the real --

MR. ELFERING: I guess consider it this way. How many recalls would have there had been if nobody would have held product? Would that number have gone up significantly and then identify who those facilities would have been.

MR. GOVRO: Am I correct in assuming that we're talking about developing some sort of mathematical system where we have lots of weighted factors that move in and out in sort of an answer to Charles' question, you know, how soon are you out of the doghouse? Well, you know, I would see that on the sliding scale and mitigated by other factors that you might put in place and so --

MS. ESKIN: I mean what we're trying to do here, I think, is identify all those factors that we think should go in the equation, but throw them all to FSIS.

MR. GOVRO: But we are talking about an

equation. That's my question.

DR. MASTERS: I think -- this is Barb Masters. The very first day, or the very first meeting we brought to you the idea that we would ultimately want plant -- risk measures around the plant, risk measures around the product and risk measures around the process, and at some point we would put all of that together so that we could individually look at all of that put together and then we can make determinations. We said we wouldn't always have at this point in time our inspection personnel going to every plant every day but that we would -- how much time they should spend there and what they should do when they get there could be determined by plant, product and process and that's a higher risk with the plant, product and process. They might spend more time doing more things and the lower risk the plant, product and process, and might spend less time doing different things, and that right now they spend about the same time doing the same thing in every plant, and it's not really driven by the risk of plant product and process, and right now I think we're

talking about the risk of plants, is how I would respond, is really what we're talking about. Starting with the risk of the plants would be my biggest overall sentence that we're describing.

MR. ANDERSON: Specifically risk control?

DR. MASTERS: Right.

MS. ESKIN: Okay. So then in this area of in-commerce, is there any other factors we want to bring to emphasize this attention or any other points about recall or complaints that we think is relevant?

MR. LINK: The only thing I was thinking of was the possibility of labeling if there would be any concerns at all. Maybe you don't have any. I just --

MS. ESKIN: In what context?

MR. LINK: We just had a situation, it wasn't a meat or poultry product. It was another food product and their nutritional labeling was way out.

MS. ESKIN: Uh-huh.

MR. LINK: And a person who was diabetic ate product and then read the nutritional labeling and thought that he had got so much sugar into his system that he --

MS. ESKIN: He would go into diabetic shock?

MR. LINK: Yeah. And it ended up that their labeling was wrong, that their carbohydrate level was way off. I mean it was like -- for example, it said it had 320 grams of carbohydrate and actually it was 32 grams. So I don't know if that's a consideration and, you know, maybe you don't have a lot of that in meat and poultry products and I guess I can't think of a specific example but I'm just making the comment.

MS. ESKIN: I mean I guess you could have it with any processed product, not a raw product, because they require labeling. Using the same type of example, nutritional labeling.

MR. LINK: You don't know whether those are always going to be food safety issues. I guess nutrition is a food safety issue.

MS. ESKIN: Can be for certain people. All right. I'll put it down for something to look at.

Let's move onto 5 which is the other area -- the other enforcement actions. Again, if you look at the two page document from our binders, the chart has a footnote that says what they're looking at here is

any prior enforcement actions resulting from causes not captured by other components we've already discussed. I think I asked a question when we were talking about this this morning, and I'm trying to remember my notes here. Is that one for example that someone had a threat?

DR. MASTERS: Yeah, my example I think that was food safety related was if we went in, if there was product that was shipped that was adulterated and we had not yet done one of our routine food safety assessments. So we went in for a for cause food safety assessment, they had been implementing their, their HACCP plan and their SSOPs fairly well. So there was not a trend.

MS. ESKIN: Right.

DR. MASTERS: So nothing had really triggered anything. And we went in, and their food safety system just was not well designed. They were cooking their product well below any recognized standard and the in plant inspection personnel just weren't trained to pick that up. They were new. We were finding that particularly in the metropolitan

areas, were hiring people that had not had an education background in food safety for example, and what they said, it was an inspector that they had just hired in the last three months or something and had just not picked up that food safety design. So I don't want to pick on inspection personnel but they were new and just had not picked that up, and so we just had to suspend them on the spot without a trend of NRs. So once they picked up in that category, and there was not a food safety assessment on the books. So just a unique situation that was suspended without the benefit of food safety assessment or the trend of NRs even though the inspector had been doing a good job, the plant had been executing and so there was nothing on the books.

MS. ESKIN: So this is data, this is like a residual category of nothing else --

DR. MASTERS: Applies.

MS. ESKIN: -- applies or something else happens that doesn't apply to any of these others, that's still data that may be relevant --

DR. MASTERS: Yes.

MS. ESKIN: -- to risk control assessment.

Any other questions on this one?

MR. KOWALCYK: This is Michael Kowalcyk. I guess I'm wondering how rare is that? Is that a very rare occurrence?

MS. ESKIN: It is rare, kind of like the number of recalls that exist for -- I think Mike suggested there may only be 15 recalls that happen a year for something like allergen controls but for those establishments for which it did exist, as an Agency, we felt like it might be worth considering as a factor that might suggest that plan is not controlling risk. So it was just something that we felt like might need to be considered but it rare.

The last category that was identified in the materials we have is other components, and the chart in the binder document lists examples of this STEPS, which is the System Tracking E. coli O157:H7 Positive Suppliers database, also company testing results and another example listed here is the school lunch, Agricultural Marketing Service school lunch testing results. So again this date, these examples here,

steps that stated that is captured by FSIS but obviously the company testing results are the company's.

DR. MASTERS: Our FSIS employees do access those results and look at those results as part of their FSIS inspection procedure. So that was just something that we have talked about, and whether or not those can be considered in a negative or in a positive context, if the company is doing a significant amount of pathogen testing results and getting significant numbers of positive absent that impact or if they're getting a significant number of negative tests, that impact, and STEPS database is something that we are following up on suppliers already. So if we are getting a positive, we are going back to the suppliers. So that's something we have already put on the table. And then the AMS, Agricultural Marketing Service also does E. coli O157:H7 testing, and they do that on school lunch products, inspections, that they consider --

MS. ESKIN: You say you have access. Do you collect the STEPS material? Does AMS automatically

contact you?

DR. MASTERS: Yes.

MS. ESKIN: But the company testing results, that's not an affirmative -- let me back up. That is data you said again that emphasize employees have access to and in your situation, if there's something that jumps out of them --

DR. MASTERS: If there is a positive, then they would verify the corrective actions that the company has taken in response to those results, and if the corrective actions are not taken by the company, then they would document it with NRs. So that's kind of how they're used today.

MS. ESKIN: Comments?

MR. GOVRO: I think you would want to be careful to do this in such a way that you didn't discourage testing because negative results would then result in a penalty. I know we see this in FDA regulated products with -- and companies don't want to test for it because there's zero tolerance, yeah, and so they don't look. And I'm not sure that's a positive thing. Same thing with the school lunch

menu. If you designed it in such a way that companies would rather not take the risk.

MS. ESKIN: But isn't Agricultural Marketing Service the one that's doing the actual testing?

MR. GOVRO: They're actually doing it, but I'm just saying don't create an extra penalty by somehow piling on with this system as well.

MS. ESKIN: Right, but in this context, all the data we're talking about in theory, whatever we decide is relevant or FSIS ultimately decides is relevant is, is considered in determining their risk assessment, the risk control measurement. There's some sort of determination and that then will dictate -- I'm trying to say that it's not the grounds for, and I know it's one of the concerns, for them to be penalized or have an enforcement action specifically against them, but rather we're looking at it the context of what type of risk control measures do they have.

So again what we've just done is gone through sort of the first part of the first question which is are these all appropriate objectives for

measuring risk control, and again, correct me if I'm wrong, according to my notes and what I've heard everybody say, we have in answer to the second question, we have not recommended that FSIS delete any of these factors, these objectives and their consideration. We have tried to provide some guidance on what we think is more important perhaps and less important and what they should look at.

Then we move to the next question, is there anything that anyone believes is relevant to this determination that has not been captured by the factors laid out by FSIS or that we've discussed in the context of consideration of the factors? Kevin?

MR. ELFERING: Well, one thing and I don't know if FSIS has included this, but I do think you need to include public health data that actually has been linked to the food-borne illness outbreak.

MS. ESKIN: Right. Again, we're only looking right now, I think that's important and you should say something, but again this -- we're looking only at that data that's -- anything that's linked to -- not anything specific to this particular plant

but you're saying that's linked to a particular product?

MR. ELFERING: No, something that can be linked to a particular plant.

DR. MASTERS: Findings in commerce.

MS. ESKIN: Barbara suggested that. I'll make that clear.

MR. ELFERING: Again, the last couple of outbreaks we've investigated, we've actually been able to identify to a particular plant.

MS. ESKIN: To plants?

MR. ELFERING: Yes.

MS. ESKIN: Plant attributes, plant attribution, product attribution data. Okay.

MR. KOWALCYK: The sources of that data obviously would be the States as well as FoodNet possibly or is FoodNet -- I mean FoodNet is only in certain --

MR. ELFERING: You're going to have certain states that are, that are -- and, you know, it's only going to be as good as the State's Public Health Department. You know, every food-borne illness is

investigated. Some are going to do interviews by them, they're going to be able to identify the food vehicle better. Some of them are going to be able to -- they're going to identify, they'll get a store culture. They'll get, they'll get the microorganism that was a seal type thing, but that's as far as they'll go. We have a very progressive, I believe, Health Department that does PFDEs on every, every positive stool sample. I don't want to get into seri (ph.) type, and all of that within Impulse and PulseNet. Any sample that we get, if we're getting a salmonella performance standard sample in our small plant, very small plants, it gets -- it goes over to the Health Department so that they can analyze it. So I mean it's got to be as good as the Health Agency. But most of them, Oregon is another one with a very, very progressive Health Department, Washington State. A lot of them are very good.

MS. ESKIN: Okay. So again your point, the data that links food-borne illness to a particular plant would be relevant and FSIS considers that under the category up here of a finding in commerce.

MR. ELFERING: Yes, and even if it isn't linked to a plant, it still could have some -- I don't think you would ever want to include it in any kind of a risk-based system. I would say it's strictly limited to a -- identified to a plant.

MS. ESKIN: Identified, right. That's the only data that should be because we're talking about plant assessment, right.

Any other factors that they should consider?

MS. NESTOR: I just wanted to go back to the NRs because it seemed like we were discussing the NRs as in their present state do they have information that's valuable.

MS. ESKIN: Uh-huh.

MS. NESTOR: But if you're giving guidance to the Agency, perhaps there's some modifications to the NR process that you can suggest so that when the Agency starts using this data two years from now, it will be there. I mean I don't --

MS. ESKIN: We can also tag that as a point when we make our comments about the NRs, that that's something to consider.

Yes, Kevin.

MR. ELFERING: Sorry.

MS. ESKIN: That's okay.

MR. ELFERING: I just keep thinking of all these things. We post -- everything that we get samples of, you know, we'll do surveys of products. For example, now we're doing a survey on poultry and identifying salmonella and Campylobacter and we're also looking at anti-microbial susceptibility. So we post all that on the eLEXNET when we get a positive salmonella. So USDA has that data from eLEXNET but do you get that from other States that do surveys of meat and poultry products?

DR. MASTERS: Some, not all.

MR. ELFERING: But there again, that would be something that a lot of States do, they do surveys of -- maybe they'll even do just a ground beef survey for E. coli and --

DR. MASTERS: Again, this is not plant specific. This is more --

MR. ELFERING: No, this would be plant specific, the ones that we're doing. The poultry

products are -- you know, slaughterers are not doing any cut up of poultry anymore. So the establishment number is right on the pack, and so this would be plant specific as well.

DR. MASTERS: Do you capture that now?

UNIDENTIFIED SPEAKER: I don't if that's done --

MR. ANDERSON: Yeah, we can look that up. To my knowledge, we're not capturing any raw products salmonella data. It's in-commerce, that way in retail.

MR. ELFERING: But then again we are doing like listeria. We do listeria sampling in delis, and if we have, if we have impact product and we can, we can -- we have product from the -- and we also have impact product where we can identify the plant, then we'll report that on our laboratory data --

UNIDENTIFIED SPEAKER: Ready to eat.

MR. ELFERING: -- a ready-to-eat product out of a deli. As a matter of fact, we've got a deli closed right now because of listeria. And we'll do additional testing of other impact product, and if we

would find a positive on an impact product, that would also be posted on the website.

MS. ESKIN: Okay. Can you repeat what you've just said seriously in a more telescope manner that I can add it to this list of --

MR. ELFERING: Any data that's collected by States --

MS. ESKIN: Any data that's collected by States --

MR. ELFERING: -- especially products that are fully cooked and ready to eat --

MS. ESKIN: -- especially RTE, you say any data related to --

MR. ELFERING: Pathogenic organisms.

MS. ESKIN: Any data collected by States relating to pathogen testing of products.

MR. ELFERING: Fully cooked, ready-to-eat products.

MS. ESKIN: Fully cooked RTE. Got that. And then this is data that we think FSIS should take a look at.

MR. ELFERING: Definitely.

MS. ESKIN: FSIS doesn't collect the data but you all do.

MR. ELFERING: Yes. We report it to FSIS but I think we're probably unique in that regard.

MS. ESKIN: Right. You don't -- right. You do it on your own.

MR. ELFERING: But you'd have to reach out to the other States that are doing the same or similar type of surveys.

MS. ESKIN: Okay.

MR. ELFERING: It could be really, you know, pretty explicit on what type of data they would really want. You know, if they don't want raw poultry salmonella data, but if you'd ever want it, it would be something that would be available as well.

MS. ESKIN: But you're saying specifically mentioned, fully cooked, RTE product, but you're saying there may be other.

MR. ELFERING: I don't know if you would be interested in it. We're doing a study mainly on Campylobacter and salmonella for anti-microbial susceptibility. So that's more of a research project

that we're involved in.

MR. ANDERSON: If the committee brings it forward, working groups will look into it. It sounds like a reasonable recommendation. These programs, I'm not familiar with, but they sound reasonable. It sounds like a good idea.

MR. GOVRO: I have a question. Maybe Kevin can answer this. Are the forms that the State programs use identical to those used in the federally inspected plants? I'm just thinking about data collection and --

MS. ESKIN: The States doing the inspecting you're saying?

MR. GOVRO: Right, in the State programs. Or are they just equivalent?

MR. ELFERING: Ours are not, but we're probably gathering the same exact data. We're going to be gathering the establishment number, the name of the plant, and pretty much all the data that FSIS would be collecting.

MR. GOVRO: I'm just thinking about data entry and, and, you know, the obstacles to --

including the State programs in this?

MR. ELFERING: Well, I think you'd have -- we'd need to look at what -- at the fields that are the most important to FSIS, and that would be the plant, the analysis and whether or not it would be positive or negative.

DR. MASTERS: This is Barb Masters. Certainly they do pathogen testing. They do food safety assessments. They do in-plant inspections. I mean they do the same types of activities.

MR. ELFERING: We just use different -- we use the same NRs and a lot of the documents that we use but because our laboratories are a little bit different and the lab people always --

DR. MASTERS: Right, their own forms.

MR. ELFERING: -- they want it done their way.

MR. GOVRO: Yeah, and that's one of the big problems with the laboratory reporting network is they don't always use the same tests, they don't report results the same way and it doesn't always merge real well.

MR. ELFERING: One thing with the eLEXNET is we're trying to get data that's entered in, so everybody is calling everything the same thing, so if you're sampling a product but you're all calling it similar, but we sample exactly the same as the HACCP categories. So we don't submit a roast beef sample. We submit a fully cooked, ready-to-eat sample that is roast beef. So we categorize them the same as what USDA categorizes them.

MS. ESKIN: Any other comments on this last part of the first question? Anything else to be considered or added?

We can now go onto number 2. The first part of the question, are some components more important, better indicators of risk control than others? I think the consensus here is yes, which leads us to the next question, if yes, should more important components have greater weight in our numerical control measure than less important measures, and I'd also venture to say the answer to that is yes. You don't expect us to tell you which ones now, do you? I think what makes sense at this point is just identify

maybe the things that are more important?

DR. MASTERS: Right.

MS. ESKIN: One or two or three of them unless anybody wants to propose a ranking system off the top of their head.

MR. LINK: I have a quick question. When you say you're trying to get to the numerical control measure, are you trying to get to a number to assign to a plant and say you're 89.2.

MS. ESKIN: Or a score?

MR. LINK: Yeah, is that what we're trying to get to here?

MS. ESKIN: I'm saying numerical.

MR. LINK: When you say in greater length to get to some numerical control number, is that what we're trying to get to ultimately?

DR. MASTERS: I don't think we have a complete vision in mind. I think that's what we'll be working with, with Resolve, to get to some ideas. I think at this point, we're just trying to come up with a conceptual framework so that we could -- it's hard to write into writing a question. We're working

towards a risk assessment type approach and so we were trying to come up with the question so that you would get the idea that we wanted to weigh the factor more than another.

MS. ESKIN: Again, any comments of the things we've discussed already. You don't have to assign it a specific number but are there any one of these factors that we think we really want FSIS to know we think are particularly important -- is particularly important?

MS. NESTOR: How many plants are not subject to any kind of pathogen testing by FSIS?

MR. ANDERSON: We actually looked into that the other day because this question came up, and federally inspected plants subject to HACCP Part 417, it looks like there are something like 2,000, maybe 2500 plants that are -- that none of the products they produce are subject to any of our pathogen testing programs. It was surprising for us. We looked at it a couple of different ways and that seems to be the case. For example, establishments that produce only raw not ground products and nothing else, and you

don't slaughter, aren't subject to any pathogen testing program. We have no performance standard for such products.

MS. NESTOR: So you've got to knock them out of your -- if you're rating pathogen testing, right?

MS. ESKIN: Does anyone want to start out and propose one of these things -- one of these factors we've discussed already that was importantly important or maybe the opposite, that may not be as important as others. I just want to give them some general response from us? Mike?

MR. KOWALCYK: At the risk of sounding like a copout, I don't think we have enough information to make that determination. I mean I think we have a good sense of, you know, the pathogen control measures, that testing is critical but really until the Agency can come up with a way to reliably and consistently gather the data in a way that you cannot necessarily scorecard, but it can categorize plants according to risk, based on these dimensions, I think it's really too early to tell without some additional analysis to understand what all the data is and how it

would be managed and collected.

MS. ESKIN: So that we are not able to rank or at least --

MR. KOWALCYK: After some research, you may find that NRs for example may be very indicative. However, because of some subjectivity in the way the reports are written, in the way the data's gathered, when it comes into practice, it might not be useable. So that's something I think is just too early to tell unless someone in the Subcommittee has more information that can shed light on that. I struggle with that just coming up -- to answer your question.

MS. ESKIN: Pat?

UNIDENTIFIED SPEAKER: Yeah, the thing I would want FSIS to look at would be the amount of production that the plant is putting out?

MS. ESKIN: You're saying production volume?

UNIDENTIFIED SPEAKER: Yes, the volume because I think that you have smaller plants that combined together are not putting out as much as your larger plants and the larger plants because of their wide distribution is going to have more public health

implications. So I would think in your risk-based scheme, you should look at how much the product volume is being produced on a regular basis.

MS. ESKIN: That should be one of the factors going back up to question one.

UNIDENTIFIED SPEAKER: I'm sorry.

MS. ESKIN: No, no, no, I'm not, I'm not scolding you. I just want to say where it goes, and the instances of things that should be considered, the production volume. Is there a reason why -- I'm just wondering -- why it wasn't addressed or at least doesn't look like it was addressed by you all in --

MR. ANDERSON: If I may actually. Don Anderson. If you'll look at your second slide which is actually the three piece slide of the November presentation, remember, it's important, and I should have discussed this before but it's easy to forget. It's important to remember that in risk-based inspection we're considering the number of elements or things that go to the actual risk, whether an establishment may pose to the public. Some of those elements have to do with risk control, how well the

establishments control this which is the primary topic of today. You see listed here some of the other elements or risk-based inspection which aren't so much about risk control as they are risk, inherent risk, by the virtue of product, species, perhaps production volume as a proxy to exposure potential.

MS. ESKIN: Okay.

MR. ANDERSON: These are all things that we are considering risk-based inspection but we narrowed our discussion or tried to today to measure risk control.

MR. ELFERING: So, for example, if you had a company that all they were doing was thermal processing, canned product, you certainly couldn't look at them at the same risk as someone who's producing lunch meat.

MR. ANDERSON: Well, I don't think we can answer today which processes or products --

MR. ELFERING: But you're going to have to look at each of them differently?

MR. ANDERSON: Yes, indeed. We would consider -- that would be considered a process risk,

and we would recognize it. We think some processes pose higher risks intrinsically to the public than others do.

MR. ELFERING: Uh-huh. Definitely.

MR. GOVRO: I would almost feel like I would need to see a starting point for a formula before I could comment that this should be higher, this should be relevant. It's very difficult to do in general.

MS. ESKIN: Okay. Then let's go to the last question here, and that is should findings from food safety assessment or other sources that indicate exceptionally effective risk controls be allowed to lower or improve an establishment's risk control measure?

UNIDENTIFIED SPEAKER: Can you repeat that question?

MS. ESKIN: I'd be happy to.

UNIDENTIFIED SPEAKER: Should findings from the food safety assessment or other source that indicates exceptionally effective risk controls be allowed to lower or improve an establishment's risk control measure?

MR. LINK: Does that mean that there's an incentive for a plant to perform at a better level?

MS. ESKIN: You're asking me?

MR. LINK: Is that what that means?

MS. ESKIN: Is that what that means?

MR. ANDERSON: This is probably one of the more abstract components and I'll try to explain it. One of the questions came up earlier as to food safety assessments and how we assess the effectiveness, the intrinsic effectiveness or the applications of a food safety system. Under the current food safety assessment system, when a food safety assessment is conducted, there's three possible outcomes that are summarized. One is that they conducted a food safety assessment, and they didn't find anything negative that they need to comment on.

A second sort of generic finding is that we conducted a food safety assessment and we noted some noncompliances or some issues either in the design of the implementation that we think -- that rise to the level of kind of noncompliance or possible deficiencies and those are typically noted with NRs

that are written by inspection program personnel, an exit if you will.

The third finding isn't as serious which is there is more considerable problems here and design issues and an enforcement action. I know an enforcement is written at the conclusion of the food safety assessment. I think that's a fair summary. So -- but there is this, this -- fortunately in many establishments and most establishments when food safety assessments are conducted, they fall into that first category which is there's no need for immediate enforcement. There's really no documentable noncompliances but I think the question you're asking, for example, is all establishments that fall into that first category, are all their food safety systems equally good because they meet regulatory requirements or are some more robust than others, are some better than others and should we acknowledge that somehow in our system?

MS. ESKIN: Or maybe back to what you were, Charles, earlier, if an initial assessment wasn't wonderful but then there was improvement, should that

somehow be reflected?

MR. ANDERSON: I think that's there in the third example that's come up is that if an establishment has its own very intensive, very scientifically valid sampling program, and they make those results available to FSIS, you know, here are the results of our sampling program and it is shown that their pathogen control by their own records are extremely good, is that something that we should consider in allocating inspection resources? I think we could name other examples but those are some I'll put out.

MR. LINK: I think that kind of falls into the -- when you're looking at the food safety system design and trying to understand what a plant is doing, you will find Plant A doing 100 things and Plant B doing 2. They may still get the same result. One's just doing a lot more stuff that kind of hedges ahead a little bit but maybe it decreases the risk and so, yeah, I think you really have to take that into consideration when you're trying to figure out, you know, what, if this guy's doing so much stuff, do I

really need to be here as much as I need to be over there. So I think the answer to your question is, yes, you should -- there should be some I hate to say incentive, but some benefit for going that extra mile and, and decreasing that risk like total quality control system.

MR. GOVRO: I think the answer is yes, if you can pretty clearly define what the criteria is for achieving a higher level.

MR. LINK: I think part of the problem when you get too far out there with these systems, they get a little hard to understand and then they don't fit into the mold of what you think it ought to look like and causes a bigger problem than it should be. So there's a lot of education around I think understanding what really is a better or more robust approach just because it might be different.

MS. ESKIN: Pat:

UNIDENTIFIED SPEAKER: Just a question and I don't understand all of this -- but it would seem to me you're basically breaking things into three categories, those that are regulated establishments,

those that are sort of middle of the ground, and then those that are not acceptable. Did we ever determine the percentage of how many of our establishments are good? Say 10 percent of those are and that we have 30 percent, you know, in the middle, I mean have we ever got those numbers together? Are we going to then test the cream of the crop at 10 percent to just monitor and make sure that they are still being cream of the crop? You see what I'm saying, and then take the middle ground and say there's 20 or 50 percent of those and test 50 percent of those plants to make sure they're still the cream of the crop, and the same with the last category. So that you don't end up with a situation where the cream of the crop get in there and then there's no way to, you know, monitor them, because there are -- people make mistakes. All people make mistakes. So if plant is on a risk-based system, from looking at our category individually and monitoring them, several of them having just become self-monitoring, you know, once they hit category one let's say.

MS. ESKIN: You're suggesting that whatever

category you're in, you are going to be subject to continued oversight --

UNIDENTIFIED SPEAKER: Yeah, yeah.

MS. ESKIN: -- and not simply, there's one determination and then it's sort of status indefinitely.

UNIDENTIFIED SPEAKER: I just think it's a tad dangerous to do that because people are people and plants are plants. You know what I mean? And they function when there's a little bit of oversight and set up because then you can move people into the next category. As long as you're not totally reaching the category where, okay, you've got the gold star now and you don't have to be monitored as much once every two years or once a year, whatever your strategy is.

DR. MASTERS: This is Barb Masters. I think that that's actually excellent input and that's kind of what we're doing at this meeting as we're starting with one piece of the puzzle as we introduce Resolve as members of Resolve are going to be a third party facilitator, and we're looking at the fact that we're having to define the measures of risk control in

plants, and that we're also going to have to define inherent risk of the product process and then we'll have to define the decision criteria that inspection personnel would have to apply once we determine if this is the route that we want to take, and we recognize that we would still have daily presence in all of our processing establishments and that right now, and Ms. Alfreda Dennis is one of our inspection personnel that's in plants every day and while she doesn't have to spend exactly the same amount of time in every plant on her assignments, but now she is driven by a schedule that tells her how much time to spend in every plant and she does exactly the same activities in every plant.

And what we're looking at is moving towards a system that instead of her not having any rational basis to spend any -- a different amount of time in different plants doing different activities in different plants, we're asking the question, could we have a rational basis for her to spend a different amount of time in different plants based on their ability to control risks in those assignments so that

she might do something different at one plant versus a different plant. And so actually you just gave us some excellent input as to what kind of criteria she might use if one of those plants were the cream of the crop. I think we just got some good input if we did say, maybe we could do something based on them being cream of the crop, I think we just got some good input that even if we did say we could do something different there would she still have clarification activity to make sure they're still cream of the crop. Thank you for your input.

MR. TYNAN: Can I interrupt just a moment?

MS. ESKIN: Yes.

MR. TYNAN: We have a time limitation on this room of 5:00.

MS. ESKIN: Okay. Are there any other comments on this last point? Again, I think everyone seems to agree that the answer to the last question is yes, that is to say that there should be some recognition of exceptional -- exceptionally expected risk control, we would just want to make sure that those criteria were well defined.

UNIDENTIFIED SPEAKER: With oversight.

MS. ESKIN: With oversight. Okay. So the question now is how -- what's the best most effective way to write up the responses to the questions. I actually took pretty, I hope, thorough notes, and I noticed that you other people did. I'm trying to think what's the most effective. One option would be divide it up and have each of us draft something. Another option was maybe to make a Subcommittee of this Subcommittee to quickly in the next 45 minutes take these notes and distill them down to answers, and then we'll all reconvene either before that -- before the 5:00 hour.

UNIDENTIFIED SPEAKER: Sandra?

MS. ESKIN: Yes.

MR. ELFERING: Has she been taking notes as well? I forget her name. I apologize.

MR. TYNAN: Toni.

MR. ELFERING: No.

MR. TYNAN: We're sort of waiting for you.

MS. ESKIN: I mean, I'm more than happy to take my notes and type them up right now, right here,

not because I think they're wonderful but because I think at least I have I think almost everything here. The question is timing. If anyone else has taken notes among the group, it could be all of us if we want or just some of us, could start right now and type them up. Then the question is we need to all look at them together before we present them tomorrow. So then we've finished the whole thing up and adjourn in a half an hour and print them out. Maybe better yet, print them out as we answer the questions, meaning do the first one, do the second one, do the third one or in the reverse order.

MR. ELFERING: I would say have your notes typed, and then let's get a copy and then we can actually work on putting together those words that we want to use.

MS. ESKIN: All right. I must confess it probably would be easier for me just to type them. Let's not use the assistant here.

MR. TYNAN: Tony is looking very despondent here.

MS. ESKIN: You can help. You can help.

All right. What I'm likely to do then is work backwards actually because I think the second and the third questions are relatively short and then while we're looking at those, it will give me a few minutes. I'll type up -- what I propose doing on the first question, the answer the first part is yes, we think these are all appropriate, and then I'm going to include just in bullet form the three or four points that we identified for some of them, not all of them. In some instances it was one for each of those categories.

(Whereupon, at 4:30 p.m., the meeting was concluded.)

C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

NATIONAL ADVISORY COMMITTEE ON

MEAT AND POULTRY INSPECTION

SUBCOMMITTEE NUMBER 1

MEASURING ESTABLISHMENT RISK CONTROL

FOR RISK-BASED INSPECTION

Washington, D.C.

May 23, 2006

were held as herein appears, and that this is the original transcription thereof for the files of the United States Department of Agriculture, Food Safety and Inspection Service.

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Jack L. Becker, Reporter

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