UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

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PRODUCTION VOLUME AND ITS ROLE IN RISK-BASED INSPECTION

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A CHARGE FROM FSIS: QUESTIONS FOR CONSIDERATION IN BREAKOUT SESSIONS

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BLUE GROUP BREAKOUT

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April 25, 2007
10:45 a.m.

George Mason University
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Room 269
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Arlington, Virginia 22201

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American Meat Institute

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I-N-D-E-X

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

(10:45 a.m.)

MR. SEWARD: This Nona Compromise allows incentives. I'm trying to just use a couple of words, that allows a large establishment or a small establishment with good controls to achieve the lowest level of inspection.

MS. SCOTT: This is Jenny Scott. It essentially allows all plants to achieve all categories, all levels of inspection.

MR. SEWARD: Okay. I didn't see it here. This would allow all -- so that's a disadvantage.

MS. SCOTT: Yes.

MR. SEWARD: It does not allow, I'll just put on here, allow all plants -- what I heard him -- this is Skip Seward. What I heard him say was that the two components would be calculated independent of each other and not combined into a total score. Is that what you heard?

UNIDENTIFIED SPEAKER: Right.

MR. SEWARD: So I don't know if that's an advantage or disadvantage at this point. It's

difficult to know since we haven't seen the algorithm but I think maybe we ought to use it as a disadvantage or use a question mark and say we don't know the --

UNIDENTIFIED SPEAKER: Algorithm.

MR. SEWARD: The algorithm is unknown unless it's the same as here but just keeping them separately.

MS. SCOTT: I don't see that as a disadvantage though.

MR. SEWARD: It's a question.

MS. MACZKA: They're not actually putting them together. They're keeping them separate, the one you have inherent risk and --

MS. SCOTT: This is Jenny Scott again. The disadvantage to the Nona is that volume is still tabulated as part of inherent product risk which really isn't where it belongs.

COURT REPORTER: Can I remind you to identify yourselves when you speak please?

MR. SEWARD: In this, we still did not address it.

MS. SCOTT: Jenny Scott. We did not address

that and -- but industry does have a proposal that Joe didn't bring forward here because it's not fully refined, but it follows the Nona approach in that there's an inherent risk measure, there's a risk control measure and then there's a volume factor added to that. So the three factors are separate, and to that extent, they're similar. But as I commented at the mic, you can't tell from any of these plans what the real impact of volume is other than we go through and look at actual calculations and the April 2nd one, you can see that it is not an equitable calculation with respect to risk.

MS. MACZKA: So would you suggest some way to demonstrate, you know, -- impact.

MS. SCOTT: That was Carol Maczka.

MR. SEWARD: If we've exhausted this because we can't think of any other advantages or disadvantages at this time, what about the changes that you'd like to see made under these approaches? And I think a lot of that comes out of the disadvantages, right? So I'm not sure how you want to exactly address that.

MS. SCOTT: This is Jenny Scott again. On the second approach, however volume is applied, it needs to be a more equitable approach to plants that have good risk control measures which are effectively reducing the risk to public health, should be allowed to achieve lower levels of inspection.

MR. SEWARD: I'm not sure if that captures it. This is Skip Seward. That would apply apparently to the second model, too. The equation is the same as Carol stated, right? Anything that -- wants changed for April 2 would be a change potentially for that as well. Do we want to think that this change, the change should be to, you know, create the diagonals so that plants can achieve -- any plants can achieve a lower level of inspection? That's essentially what you said.

MS. SCOTT: Yeah, this is Jenny Scott. And I think that that should be a change to the Nona that all plants should be able to achieve all levels of inspection, whether you do that through the diagonals in the Nona Compromise or some other means. It's very important. And the bottom line is that the hazards

are not present due to good risk control measures, then there is no impact, no negative impact on public health and that's what we're trying to achieve.

MR. SEWARD: Anybody else? Ideas for either advantages or disadvantages of the April 2nd model, FSIS model, the Nona model that was shown to us as a one page PowerPoint or the one presented by Joe Harris. We're looking at the advantages or disadvantages or any changes that need to be applied to those.

MS. SCOTT: And the change for the Nona Compromise. This is Jenny Scott. Joe didn't fill in the details. It still needs to be worked out but we need a better description of how volume would be incorporated into the Nona Compromise.

MR. SEWARD: In the equation, right?

MS. SCOTT: How it is applied to those boxes. This is Jenny Scott again. I think it could be an advantage to having separate inherent risk, risk control measure and volume, and there ought to some matrix to apply to them. Right now they're not separating volume. It's still incorporated in the

inherent risk measure, correct, Don?

MR. ANDERSON: That's correct.

MR. SEWARD: Any other thoughts?

MS. MACZKA: This is Carol Maczka again. In the Nona Compromise, are they taking volume and are they taking -- trying to put it into risk control measures? I mean --

MS. SCOTT: This is Jenny Scott. What we've been working with is something that had three components, inherent risk measure, RCM and volume, and the way we've been trying to do it is with those three factors added to it. And so then you would have a total number of points based on the points that you've achieved in each of those categories. Then what we haven't done is decide where we divide or separate the points, and I think it may be something like 0 and 50, and your level of inspection do that, the 3 levels of inspection are applied or whatever. We didn't get to the mathematics of how you would put a certain percent of your plants in level 2 and then in level 1 and then into level 3. We're a little mathematically challenged.

MR. SEWARD: So it's really not -- this is Skip Seward. Volume is really not important to establish risk measurements. It's a separate thing if you will.

MS. SCOTT: That's what I'm trying to think of --

MR. SEWARD: Well, it depends on, you know, the version but --

MS. SCOTT: Yes.

MR. SEWARD: -- anyway it's not part of the PIR. That's a key.

MS. SCOTT: That's a key.

MR. SEWARD: Okay. So it could be a component or separate. It depends.

MS. SCOTT: This is Jenny Scott. How we're applying volume really is dependent upon the risk control measures. It would have a big impact if we had poor risk control and less of an impact if you had good risk control. So we were in effect waiting for the volume --

MS. MACZKA: Based upon the historical data information, would that be another reason to --

MS. SCOTT: Based on several factors that they described.

DR. GUO: -- on the risk control is no longer independent.

MS. SCOTT: Jenny Scott. Yeah, but how it would be applied in our thinking is that it would be dependent upon the risk control measure, yes. So you would -- if you had poor risk control, then all of the volume points would apply. If you had good risk control, then you would get fewer points for volume and, of course, dependent upon -- I don't have the actual calculations --

MR. SEWARD: We had a weighted --

MS. SCOTT: It was a weighted -- essentially we weighted the risk control measures based on volume. So I think that that would be a change that would make the approach would be to weight the risk control measures and the volume factor.

MS. MACZKA: You weighted the inherent risk based on volume, inherent hazard.

MR. ANDERSON: Yeah, this is Don Anderson. The inherent hazard is a mathematical function of both

volume and the inherent hazard, in either the April 2nd proposal or in the Nona Matrix that we talked about today. Inherent risk would be computed in the same way. You have volume and inherent hazard are both collected and volume in it mathematically.

MS. SCOTT: This is Jenny Scott. We would prefer to see you do that on the risk control measure side, and we're struggling with ways to do that.

MR. ANDERSON: I understand.

MR. SEWARD: Anything else? This is Skip Seward. In all three cases, as I understand it, the PIR is weighted PIR based on what you produce in your facility. Is that correct? And do we all agree that that's a good -- an advantage that we could say, you know, for all these reasons, we believe that's appropriate.

MS. SCOTT: If you have different risk of product, then your PIR should be weighted based on how much of which risk products you produce.

MS. MACZKA: Then volume would come into that.

MS. SCOTT: It is not volume itself but it

is weight based on volume. This is Jenny Scott. For example, if 50 percent of what you produce is raw ground beef which is the highest risk, then that would carry 50 percent of your PIR. If 20 percent is a fully cooked beef patty, then that has a much lower risk and you produce 25 percent of that, 25 percent of your inherent risk factor that goes into the algorithm.

MR. ANDERSON: Yeah, this is Don Anderson. I understand perfectly well what you're saying. To say that you want full volume -- hazard into risk control, doesn't mean that volume wouldn't play a role in these facilities relative to volumes --

MS. SCOTT: Yes.

MR. ANDERSON: -- to determine the weight of the hazard for the inherent risk, and in fact, you may want to start calling it inherent hazard instead of inherent risk. But relative volume would still be used to weight the hazard with an absolute volume which we can -- a proxy for exposure would be moved over if I understand what you're saying when you say risk control measures.

MS. SCOTT: Exactly.

MR. SEWARD: Don, do you see any advantage with the -- Skip Seward. Do you see any advantages or disadvantages with the concept proposed by Joe, his diagram where the boxes were not necessarily discrete or the --

MR. ANDERSON: Don Anderson. No, I don't see any, you know, I'm not sure how to put this. I don't see any particular disadvantages per se. I mean the Nona Compromise or the Nona Matrix are in effect very similar and, in fact, in kind of the middle part of the matrix. They're pretty much, they're pretty much the same. Where they change is that they -- the Nona Compromise sort of splits the upper left matrix on a diagonal to allow even the plants with the highest inherent risk to get down into the lowest level of inspection if they have exceptionally good risk control, and in the lower right-hand corner of the matrix or lower left-hand corner, it allows even establishments with extremely low inherent risk to get into the highest level of inspection if their risk controls are not very good. So it kind of -- the main

thing is it splits those two extreme cases. So that it allows more -- and today is the first time I saw it, but that appears to be the achievements.

MR. TYNAN: Well, if you think of anything else that needs to go in that, you know, let's tackle that.

What about number 3? What specific records should the inspectors use to approximate production volume for the various product categories in these approaches?

MR. ANDERSON: Yes, just a clarification. Don Anderson. That is the question we want to ask but again remember that part in Dr. Engeljohn's presentation where he emphasized, and I think he did it twice at the beginning and the end, Dr. Engeljohn emphasized that establishment personnel, for the same reasons that we at Headquarters are not allowed to survey industry without OMB approval, it turns out that our employees are also us, right, and they, too, are not allowed to survey industry without OMB approval.

So inspection personnel are not allowed to

ask plant management how much of this do you make, how much of that do you make, but what they are allowed to do, two things. They are allowed to, one, they're allowed to access, observe and look at all the records that the law allows us to look at, and I'm not the expert on that, but the point is they are allowed to review available records to help them, the IICs, to come up with estimates. And number two, as Dr. Engeljohn pointed out, they're also allowed to share with the establishment their estimates. Okay. I've completed my extension today and I'd like to know if these are the estimates that I'm providing to the Agency database on volume.

MS. SCOTT: This is Jenny Scott. And industry is allowed to say, you're wrong on this, you should correct it, correct?

MR. ANDERSON: I'm sure industry is allowed to say that. It's not clear to me. We'll probably talk about it at the industry data meeting next week. It's not clear to me. I'm pretty sure that we haven't followed through carefully that process for how we would then take that information and respond to it but

certainly industry would be allowed, management would be allowed to respond and propose corrections. We may need some clear published process on how that information will then be used. Don Anderson for the record.

So the question -- Don Anderson. So the question that we're really asking is what types of records, and this is really more a question for those of you, you know, in industry than the consumer I guess, but what types of records based on your own plant's experience are available that you think that would help inspectors come up with better estimates of volume?

MR. SEWARD: This is Skip Seward. So I think the records that the inspector should use are the production records accessible to FSIS which is what they're doing now and it seems to be adequate and working and representative of what the plant produces. I'm not going to mention the process which is the review with the establishment and so forth, but it seems like those are records that --

MR. ANDERSON: Maybe for the record you can

-- Don Anderson -- you need to list two or three generic types of production records so we're all on the same page. When we talk about production records, at least, you know, in your experience, what types of production records are you referring to? Give us some examples.

MR. SEWARD: How much product do you need on a given day? What product did you make that day?

MS. SCOTT: This is Jenny Scott. Usually that is captured on some sort of quality or even HACCP record in terms of the volume being produced.

MR. ANDERSON: What you're saying is -- Don Anderson. I think what you're saying is those type of actual records that, the actual estimates of what we're trying to get at are written down in most establishments or at least in some establishments. There are written records that you go to directly what we're trying to estimate.

MR. SEWARD: I think the -- review records, say what you make --

MS. MORALES: This is Olga Morales for the record. There is a question that -- whether -- that

it could take more than just regular production. So that's something that we need to clarify before we make a decision -- review records are going -- produced that day.

MS. MACZKA: This is Carol Maczka. Do you think the questions they're asked to answer, the inspectors, how much of the product was shipped that day --

MR. ANDERSON: Actually on a typical day --

MS. MACZKA: On a typical day --

MR. ANDERSON: -- how much product is shipped.

MS. MACZKA: And then the second question is how much has been shipped in the last 30 days?

MR. ANDERSON: That's correct.

MS. MACZKA: So if you're going to ask these questions --

MR. ANDERSON: Excuse me. Not how much has been shipped in the last 30 days but how many days was that product shipped in the last 30 days.

MS. MACZKA: So maybe the time records to the kinds of use -- what records would be used, maybe

it shouldn't be tied into answering either of those questions. So in answer to the first question what would they use to answer that question.

MR. ANDERSON: Okay. That's --

MS. MACZKA: I mean I think it takes a certain kind of meaning.

MR. ANDERSON: Right.

MR. SEWARD: Skip Seward. I think when the question came up and you sort of restated about whether it's been shipped or not, I'm trying to understand the importance of that because this is about risk-based inspection to deliver the market inspection on products which is achieved at the -- review to make sure that -- and so what happens to that product subsequent to that, I'm trying to understand the relation between that and the level of inspection that's being exercised in the facility. If you're trying to get to the exposure part of it and how much of it goes out, okay, maybe but I don't understand the relevance of whether it was shipped or whether it's in the freezer or to the level of inspection that's taking place during the production

of that product because after it's produced and has the mark of inspection on it, the inspection requirements, whether it goes in the freezer for a year or six months or whatever, is somewhat -- it's a different question that doesn't have much to do with risk-based inspection in terms of the allocation of resources. So I understand that you want to give an approximation of that but as Dr. Raymond said, to a certain extent that's going to level out over time, to get a picture of that. So most facilities really don't want to carry a year's worth of inventory in their freezer nor could they afford to do that because that's product that they've invested money in and haven't sold or having moved it out to collect the revenue. So it may occur that most people are interested in moving product through the system as quickly as they can. So I think the relevance of that is something that could be discussed further.

MS. SCOTT: This is Jenny Scott. If you think about what we're doing here, what's going on in the plants on a day-to-day basis, you can't really game the system very well to shift your stuff into

another category of inspection very easily because the only way I could see you could do that is a factory -- both raw and cooked poultry. And I'm going to freeze raw poultry and I'm not going to ship it. So it doesn't figure in my calculation and I get a lower rating because it's only the cooked that enters into that. But it's unlikely that plants should be able stay in business and shift around to that extent. So I mean we don't need absolute numbers, whether you're producing 50,000 pounds in one month and then 30,000 the next month, it's probably not going to make a major difference in how we're adjusting things here. Maybe some examples would help on that.

So I think that this is an issue that we have to grapple with and come up with a solution but I don't think that -- I think that we're making more of it than needs to be frankly.

MR. SEWARD: Skip Seward. This might be a great source where the industry data could take over because there would be nothing I suppose to stop industry from generating a voluntary form of production that no one's asking you to fill out but if

industry decided they're going to take the check sheet that looks like what it is that FSIS is interested in and they can certainly supply that on a voluntary basis at a weekly meeting or whatever, and if the inspector wanted to go through and double check against production records, and get a sense of whether that's correct, that would be an opportunity for them. So we might want to say what specific records, and we might just want to say it's an opportunity for industry data sharing. Do people buy into that? Do you see how that might work? If they're going to collect the information anyway, it might be something that would be easier for them to do and probably save time, too. So can we put that down and speak to that?

MS. MACZKA: Yeah.

MR. ANDERSON: Don Anderson. While you're writing that down, I agree with that and again I can't recall what is on the Agenda specifically for the industry data meeting, what we're calling the industry data summit, same time, same place, same Monday, and I think that probably industry volume data is a topic for discussion. If it's not, it certainly should be

brought up.

MS. MACZKA: I do have the agenda.

MR. ANDERSON: And is there a place for that?

MS. MACZKA: Well, you move from like -- they get your idea for discussion, but basically they're talking about quality. They're talking about the mechanism by which to get the exchange, get the dialogue going, and then Dan Engeljohn will talk about getting some specifics.

MR. ANDERSON: Okay.

MS. MACZKA: But it's more -- it's not really anything into --

MR. ANDERSON: Okay.

MS. BRESLER: This is Faye Bresler. I have a question for the folks here from industry twofold. Dan Engeljohn had a pie chart that showed establishments that produce different types of product. So one question I have is what impact would seasonality on making those food types of products have on the volume of production? And also, how could possibly the volume of production vary between those

establishments that only produce one product and establishments that produce multiple, more than five?

MS. SCOTT: This is Jenny Scott. Fay, that's a very good question, and I think this is where we would need to look at some actual examples of how we would introduce the product but the product that tends to be produced on a seasonal basis which probably produce a lower volume than those that's produced year round. I think some of the raw products would -- the ethnic products are really seasonable. We have to go through and see if we can figure out what some of the different production types are --

MR. SEWARD: This is Skip Seward. Certainly if you went down this pathway, then that could just be the monthly type of process. And so, you know, at the monthly -- at your final weekly meeting with inspection staff, you know, when you pull out your voluntary form and say, here's my projection for next month or there's what will change, it would just be a simple process of updating that projection for the month ahead and then if we needed to update the Profile or whatever, it could be done. That would be

one option.

But what I think I heard was the inspection staff currently at some frequency may say a review in order to assess whether or not there is a change in the production at that facility for a variety of reasons, you know, the type of samples that are being tested that month or -- and those types of things. So it's sort of incorporated into what they already do but, you know, either way, I think to capture that is important, right, because next month there's a big push on hot dogs and hot dogs go from 50 percent of your production to 80 percent of your production, you probably want to know that, you know, to see if that impacted it. So I think you can capture that in some frequency of trying to do that.

MS. BRESLER: Fay Bresler with a follow up question. Would an establishment that makes more than five products compared to an establishment that makes one product have five sets of production data or production records or -- that potentially more -- a greater impact of inspector time to review those different production records?

MR. SEWARD: Okay. Let's go on. If you have any comments, you can jump in, but what about other suggestions of how to factor in exposure into assessing the risk presented by an establishment?

MS. SCOTT: This is Jenny Scott and this is just off the top of my head but I remember from past meetings that the way you're looking at volume now is almost historical, what happened in the past, in creating your inspection resources based on that. If you think about increased production of certain types of products in certain seasons, or you might produce a meat product in another season, the consumer groups made a comment in the past that if you're going to introduce a risky seasonal product, then would you want the inspectors to be there at that time which you might not capture by the current approach. So this comes back to another opportunity for industry to share its information with the inspectors to deal with it, and I'm not sure how we figure it into our boxes or things like that but, you know, I'm a small plant and I only make hot dogs over the period for production for July 4th or a special type of sausage

during a certain time of year. Then we would want to be able to let the Agency know that we're going to produce this higher risk product so they can make an adjustment to their inspection.

MR. ANDERSON: Don Anderson. Just -- not a clarification but actually a -- operation. I do want to make sure that everybody understands that this is a good benefit, that we'll all agree that the volume data as Dan explained goes into the PBIS extension. When an inspector conducts inspection on a given day or if they do extension work on a particular day, it goes into their computer and then as soon as they synchronize their computer with the headquarters' system, which usually is the same day. It's almost always within a few days, when they synchronize their system, their laptop with the PBIS system at headquarters, the extension data loads into the Agency's database in Washington, and then that night, that very night, a program will run that will grab that new extension data and computer new inherent risk measures which would be, you know, be available to the inspector the next day. Now it hasn't been clear to

us that we would want to give the inspectors every day updated information because, you know, we don't want to overload people with information either. But the point is that the volume data in the extension can be used in almost real time and will be used in almost real time and computer a new inherent risk.

MS. BRESLER: Faye Bresler, kind of going back to what Jenny Scott said, following up with Don Anderson's comment, Jenny, you presented what we would be a prospective assessment that there is a plan, whereas the current system is retrospective and there are a lot of issues involved with both systems. Just laying it out --

MR. ANDERSON: It is interesting -- Don Anderson. It is interesting though that one could envision, and I'm not proposing this, but one could envision changing the wording of the question in such a way to say that the, you know, on a typical day, how much do you produce and in the last 30 days, how much did you produce? You could ask the inspectors, if we thought they could answer it and so forth, we could ask in the next 30 days, which products are you going

to produce and in what volumes? And that would make it prospective.

MS. SCOTT: This is Jenny Scott. Again, that comes back to industry data, if we -- there, and most people tend to know what they're going to produce the next month because of fulfilling orders, but that can change if you get a last minute order but that might be an approach to consider because it all hinges on the Agency being able to use data that is industry supplied.

MR. SEWARD: This is Skip Seward. What about in this area, it seems to me that this is where finished product sample results, you know, if you're talking about instant hazard in the food after it's been produced or by exposing the public to that, it seems like contact or exposure, it seems like to a certain extent with that exposure, that would be related to a greater extent to a microbiological profile of the finished product. So whether that's having the verification results that are in the establishment risk control factor but when you're talking about exposure, the more often an

establishment produces food and ships it that's contaminated with *Listeria monocytogenes*, the higher the exposure is from the product. So maybe we ought to capture something in here that just finished product pathogen test results, product has been shipped, you know. Do you think that's something we should capture here? I mean to me that's what exposure is. So it's --

MS. SCOTT: This is Jenny Scott. It comes back to how industry data might be used to better refine the system and capture the exposure to hazards that are --

MS. MACZKA: Yeah, this is Carol Maczka, and I think that, you know, we use volume as a proxy for exposure but we know that when it comes to being exposed, it's how much you've consumed and you eat, of that particular pathogen agent and what has been consumed and how much is in there. So maybe this is a way to more fine-tune what we're doing and it would depend on industry data.

MR. SEWARD: Any other ideas or how we might factor in exposure into assessing the risk?

MS. MACZKA: This is Carol. I -- ranking just recently which was done by New Zealand and they basically looked at their dietary survey and figured out frequently consumed foods depending on the consumption angle of it, not just the pathogen level, and I just throw that out. I really haven't thought of how to tie that in but, you know, I suppose consumption as well as contamination.

MS. SCOTT: This is Jenny Scott. I think question here we're dealing with volume, is sort of implying that if you're producing the product --

MS. MACZKA: Right. But, yeah, maybe the more food they eat, the more frequently like hamburgers versus something else.

MR. SEWARD: The only other thing I can think of, this is Skip Seward, that might fit in here is, we don't have that right now, this is what we're talking about, attribution data, that links a specific product to a specific establishment. That might serve a purpose in looking at exposure.

Did you get any good thoughts while you were out of the room?

UNIDENTIFIED SPEAKER: No, none that I can share. (Laughter.)

MR. SEWARD: Okay. Anything else that anyone wants to add to the mix?

MS. SCOTT: Can I just -- going back to the original question, we didn't give a disadvantage for the Nona Compromise, and we probably should say now that how volume figures into the Nona Compromise is not yet clear.

MR. SEWARD: Okay. The algorithm has not been -- the use of volume in the algorithm is not finalized?

MS. SCOTT: Yeah, the application of volume is not finalized.

MR. ANDERSON: This is Don Anderson. I'm not sure that that's as much of a disadvantage as it is just kind of an unanswered question. It may or may not be a disadvantage. It is something that should be clarified, which takes time.

UNIDENTIFIED SPEAKER: I'm doing a time check. The meeting will begin at 11:45. So if you're finished and you want to take a break and run to the

rest room or get a cup of coffee or whatever, --

(Whereupon, at 11:30 a.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:

PRODUCTION VOLUME AND ITS ROLE

IN RISK-BASED INSPECTION

A CHARGE FROM FSIS: QUESTIONS FOR

CONSIDERATION IN BREAKOUT SESSIONS

BLUE GROUP BREAKOUT

Arlington, Virginia

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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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