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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RED GROUP BREAKOUT

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April 25, 2007
10:44 a.m.

George Mason University
Arlington Campus
Room 269
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Arlington, Virginia 22201

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I-N-D-E-X

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

(10:44 a.m.)

MS. JOHNSON: I'm LaVonne Johnson with FSIS, Office of Policy Affairs. My role is actually to record what you say and for one of you to report out on what you came up with.

Before we designate or someone volunteers to facilitate the effort, to keep the conversation going to perhaps try to reach a consensus. It's not mandatory. We can have different ideas on the board. I would like for you to identify yourselves, your name and the association or company you're with for purposes of the Court Reporter. This is Andy. So we can start here.

DR. VETTER: My name is Danah Vetter. I'm here on behalf of NAFV today, which is the National Association of Federal Veterinarians. I am public health veterinarian in plant and I'm also trained in EIAO. So --

MR. REINHART: Bob Reinhart. I'm with Sara Lee Corporation.

DR. YANCY: Alling Yancy, Y A N C Y, U.S.

Poultry and Egg Association.

MR. PRETANIK: Steve Pretanik, National Chicken Council.

MR. HONTZ: Lloyd Hantz, GMA/FPA.

MR. CORBO: Tony Corbo, Food and Water Watch.

MS. KLEIN: Sarah Klein, Center for Science and Public Interest.

MS. REISER: Laura Reiser, FSIS.

MR. CLEMANS: Sid Clemans, Office of Budget and Program Analysis, USDA.

MR. SCHROEDER: My name is Carl Schroeder. I'm a risk analyst with FSIS.

MS. BARRETT: Kathleen Barrett. I'm with the Office of Public Affairs.

MS. LOGAN: Laurie Logan, FSIS.

MS. JOHNSON: What we're doing right now is introducing ourselves for the purpose of the Court Reporter.

MR. JIANG: Baoren Jiang, Taipei University.

MS. JOHNSON: Okay. If you can, before you speak, try to say your name or say your name, so we

can get everything correct on the transcript as to who said what.

At this moment, I'd like for someone to volunteer to facilitate. Any volunteers?

DR. VETTER: Okay.

MS. JOHNSON: Thank you. Let me write on the board, let me just remind everybody, to reiterate what was said in the plenary session, that we have four questions to address and they're written on the board. And to simplify it, whatever way you want to do it because I'm helping you.

DR. VETTER: Okay.

MS. JOHNSON: You can start with the first question and start with the advantages if you'd like, but it's however you want to facilitate the discussion.

DR. VETTER: Okay. I guess we should just go through these questions one by one. I'm not sure when they say what are the advantages or disadvantages of each approach. Are they wanting us to compare the April 2nd approach to this new approach that they've now proposed?

MR. CLEMANS: What are the approaches? Can you just quickly outline the approaches because maybe I'm slow witted and missed them in the meeting?

DR. VETTER: That's what I was assuming, that they were talking about the April 2nd and compare it to what -- the pairing. So to combine the two as one total number, and then I guess also maybe this would be the time for people to suggest a different approach that wasn't discussed out there.

MR. HONTZ: That's part of question number 4.

DR. VETTER: Is that it?

MS. JOHNSON: Yes, it is.

DR. VETTER: So we'll do that in question number 4. So is that what they want us to compare, the April 2nd --

MS. JOHNSON: Well, actually I thought it was the approaches that were presented today. However I --

UNIDENTIFIED SPEAKER: We're missing, we're missing Joe's --

MS. JOHNSON: Hum?

UNIDENTIFIED SPEAKER: We're missing Joe's, you know, in writing.

UNIDENTIFIED SPEAKER: The compromise approach.

UNIDENTIFIED SPEAKER: -- the April 2nd approach.

UNIDENTIFIED SPEAKER: Okay. One copy.

DR. VETTER: So either the pair, the numbers not being a total -- greater than a total RBI number. That would be the one approach, looking at -- or this approach where the Nona complex is sort of altered. And I guess the one question I have about this one is how, how does volume relate to that? How do they weight the volume in this approach? I didn't really understand that. I understand looking at it differently as far as the Nona Matrix.

MR. REINHART: I believe what Joe said is that it wasn't defined and that this would be the expected outcome by FSIS and that would be that every product regardless of where it failed potentially to go to a level of inspection 1, and then every product would go from where it failed potentially go to a

level 3, that the controls deemed such should happen. And that FSIS would design an algorithm to define how that would happen.

I think he specifically said industry and their data tried to design that algorithm. In essence said to FSIS, this is our expected outcome as they would say to us if any EAIO were to visit, this is what you're supposed to have, go figure out how to get it.

DR. VETTER: Would you think that the pairing that they did suggest would -- I know that it didn't quite fit that picture but would be more applicable to that?

DR. YANCY: Comparing that -- I'm sorry. This is Alling Yancy. Comparing the USDA suggestions?

DR. VETTER: Yes. Where they were not combining the two to make one number, where they were saying if you were a large volume plant, but you had good risk control, then you would be in group 1.

DR. YANCY: Again, this is Alling Yancy. I'm thinking --

DR. VETTER: I'm sorry. I keep forgetting

to identify myself.

DR. YANCY: I'm thinking that the Nona Compromise, for lack of a better term, is more appropriate and I'm not sure I'm answering your question yet, but I think I'll get there. I think it's more appropriate because it gives every product type and every establishment type regardless of the amount of volume of the products for -- types of products they produce, an opportunity to theoretically fall into any one of those areas. And the Nona Matrix that was presented this morning obviously still -- there's a gap between that. And there's no an opportunity for every product type or every plant, depending on the volume of products it produces, to fall into 1, 2 or 3, and that's why I think that the Compromise is more logical.

Now how we go about, which I think now is getting to the root of your question, how we go about using volume in calculating volume to fall inside of that or the calculations by which we get to where they fall in that compromise, I think that's still up for debate. And my concern would be, of course, that we

have a program that's complicated enough to include all the potential variables within reason such that we could have a more representative calculation but not so overly complicated that nobody can understand it. Did that answer your question at all?

UNIDENTIFIED SPEAKER: Does everybody understand what -- this morning?

UNIDENTIFIED SPEAKER: See, that's what we need to do. We need to look at the advantages and disadvantages of --

UNIDENTIFIED SPEAKER: If you do a terrible job, you have a problem for a level 3 inspection scenario with their matrix. With this one, and vice versa, is doing a super duper job if you've got a high-risk product. You have an opportunity to get a break there, and again with this one, you don't. You get an incentive both ways, and if you don't your job, FSIS in the lab, you work with this, and you go after this guy who's doing a terrible job -- so that kind of takes care of these --

DR. VETTER: Danah Vetter again. Like you pointed out, it looks like what we've really got is

the one approach that was presented today because we haven't gotten to question number 4 yet where everybody can give their other ideas for how we weight volume. So in number one, it looks like we just have the one approach to kind of look at, the one that was presented today where they take the risk control measure and the inherent risk and they look at them as a pair. They evaluated two different numbers instead of one number.

So what are the -- do you want to start with disadvantages because that seems to be kind of where we started this conversation. So what are the disadvantages of the paired numbering system?

MR. HONTZ: Lloyd Hontz from GMA/FPA. From my viewpoint, this looks very much like what was presented back on April 2nd when Phil made his comment about certain establishments would never be able to get into the less intense inspection category and that still seems to be inherent in the Nona Matrix that Don Anderson presented this morning.

So in my opinion, that remains a very large disadvantage and eliminates that incentive for the

large establishment to do the very best control job that they can to get a reduced intensity of inspection.

DR. YANCY: Alling Yancy, U.S. Poultry and Egg. I agree with everything that Lloyd said but to add to that, add a layer to it, as we just discussed, it does, of course, remove the incentive but it also removes from the table the ability for the Agency to truly go after a poor performing producer who produces a low risk product. And I should think that the Agency would want the opportunity, an equal opportunity to theoretically go after or, and please understand when I use the word go after, I mean enforce the regulatory standards on a poor producing integrator, whether that category of risk involvement is high or low. And the Nona Matrix as presented this morning still leaves a gap there.

DR. VETTER: Danah Vetter again. In looking at it, and maybe I misunderstood what they were saying because in their Nona Matrix, you know, they have the three and then the two and then the three. And maybe I misunderstood because I didn't hear any specific

numbers or anything like that put out there, but I thought they were saying that if you have let's say a risk control measure of the perfect plant, like --

MR. CORBO: Joe Harris.

DR. VETTER: Thank you. -- Joe Harris presented, and they have a risk control measure of zero yet they score 100 on the plant size, that they then could be in category 1. Is that possible?

MR. HONTZ: That would be a compromise.

DR. VETTER: But is it possible under the new pairing?

MR. HONTZ: No. It would be this block up here, which is level 2. This would be the most risky and highest volume I presume.

DR. VETTER: Okay. So they would still be limited to a level 2?

MR. HONTZ: Exactly.

MR. REINHART: Just on the disadvantages, FSIS didn't outline how they were going to incorporate volume differently along that side of the Nona Matrix or that axis of the Nona Matrix. In essence, I believe Don indicated that it would remain the same as

originally proposed. So you would still end up with the scenario on that matrix where a 20, okay, a plant that is very large scores 100, and a 20 that is very small scores a 20, half of that then going into the number, the way it was originally proposed, but anyhow, for the lack of -- let's just scale, okay, 5 times difference on the axis, independent of anything that goes on in the plant and the plant's ability to control the hazards. So I believe the way the Agency laid it out, if we were to put numbers to the model as Joe Harris presented originally, the problem has not gone away. The problem is exactly the same. The only difference is they split it onto two axes, into a Nona Matrix. It is still going to be skewed very much so away from really looking at what's going on where the Agency can make a difference in the process.

DR. VETTER: This is Danah Vetter speaking again. And this is a what if, and I think it is the 2, because the way I see it is the compromise Nona Matrix, that they do apply sort of a middle level for that highest volume, lowest risk, where you have a volume of 100, a score of 100, but then there's some

sort of cutoff, and this would be up to the risk people to determine, that would still -- your risk control measure would put you into level 1. You could be 100 with a 0 or a 1 or 2, and so that would be the compromise, and so that would be -- there would be some cutoff mark in that upper left-hand corner there.

MR. REINHART: Yeah, that's exactly correct. That's what I believe Joe said, and it led to the other extreme and that is a plant that is having struggles performing --

DR. VETTER: Right.

MR. REINHART: -- along their own control measures and what they implemented and FSIS' findings in evaluating them. They too now can go to the other extreme. They could be a 1 theoretically in inherent product risk but they could now fall into a level of inspection of 3, and the reality of the world is, if you're one of those ready-to-eat low risk products, however that follows out down there, if you're failing to perform and manage the risk in your process, they're just as dangerous to the public, and just as bad an outcome. In some cases, even worse. The

consequences can be terrible as that of, you know, the other extreme of product.

So I think leaving a 3, a level of inspection 3 available to all classes of product, if the company fails to perform, it's something FSIS needs to address.

DR. YANCY: I agree. Alling Yancy, U.S. Poultry and Egg. I agree, and that's where I was going a moment ago when I answered, Danah, your question. I think the Nona Matrix as presented by FSIS still does not provide the Agency with the opportunity that I should think it would want which is to in theory have any product and any performer fall into any one of those three categories, and that's a major disadvantage to the consumer. It's a major disadvantage to the producer.

You can look at whether you want as an incentive or as a carrot or as a stick, but nonetheless, it should be available. And there didn't seem to me yet to be a clear addressment of the issue regarding the fact that the inherent risk of the product should be -- how it should be addressed and

whether that should be -- whether the product -- whether it's in the inherent risk of the product or whether it's in the establishment risk controls.

I think one of the basic understandings of HACCP is that your process controls should be allowed to or should be factored into whether you address appropriately the inherent risk of the product you're producing. That's just inherent to HACCP.

So you would think therefore under that argument alone and it's certainly not the singular argument in defense of that. Joe's made a valid one in the calculation description that he showed, but that's another argument for why you should consider the volume as part of your establishment risk controls not as part of the inherent risk of the product. And I haven't seen an addressment of that yet, not by the Agency.

DR. VETTER: Go ahead.

MR. CORBO: Tony Corbo with Food and Water Watch. This whole concept of volume, and I appreciate this discussion and how industry is trying to grapple with it. The problem that I have is a high volume

plant, if something goes wrong, if something goes wrong, it could have, you know, major, major public health consequences. And I appreciate, you know, Joe's presentation in terms of the extremes that he presented, but is there really a perfect plant out there, a high volume perfect plant. Because I am very concerned that inspection personnel are going to be reallocated away from some of these large producing plants and not catch something that may go wrong, that eventually could have major consequences to the public and that's -- and I appreciate, you know, how everybody's trying to come to grips with it. I don't have the answer to it, but I am, I am just deathly afraid that if we minimize volume in terms of this calculation, that it could have public health consequences out there.

DR. VETTER: This is Danah Vetter again with NAFV. I'm on both sides of the fence and I'll explain why. I do believe that volume is part of inherent risk because I believe it's a proxy for exposure. When we talk about volume, I think that's the correct terminology. It's a proxy for exposure, and that's

why it's part of the inherent risk calculation because if something does go wrong, there is a greater severity to what happens which is all part of HACCP as well. That's how you look at HACCP. Is the hazard there, and if it is, what is the severity of the hazard? So I do believe that it is part of inherent risk.

However, I also believe that it overshadows the other more important risks in the way that the algorithm was presented in the April 2nd meeting. I also do not agree with the fact that there's a gap. I do believe that everyone should have the ability to be in the level 1 or level 3 section regardless of size, and I think that, you know, risk control measure is the other part of that, that plays into that and what product you're producing.

So it goes back to what they were saying is how do you weight volume and how big of a role does it play? I do believe it's in inherent risk but I don't believe in splitting it up into five categories and multiplying it by five. I don't think that is representative of what is actually going on in the

plants and so on and so forth. But I think that it does need to be weighted differently than it is because it does overshadow, and I do believe that everybody should have a chance, in effect, how do you get to that point?

So just to -- that's kind of where I stand on it but just to reiterate for the group and what we intend to say about this, number one, the disadvantage is that there's still a gap. Your very small plants that are doing really, really bad can't be in that lower right-hand corner, and your large plants that are doing very, very well, still cannot be. And so is that a consensus with the group?

MR. REINHART: Yeah.

MR. CLEMANS: Presumably although they were unclear about whether a little plant would always be in category 1.

DR. VETTER: Well, it's --

MR. CLEMANS: If volume is so dominant it could never be --

DR. VETTER: Category 3.

MR. CLEMANS: -- 3. Yeah.

DR. VETTER: Yeah.

MR. REINHART: The issue -- I say there's two different questions on the table. How to deal with volume is one of the questions. But the other question is the desired outcome, and I think that we're close to consensus on the desired outcome which would be a model that resulted in a theoretical pictorial, okay, because this is not really straight lines and all that. Like the Nona Compromise would be the desired outcome by everyone. Does anyone disagree with that?

DR. YANCY: This is Alling Yancy here, U.S. Poultry and Egg. Where every product in every establishment has an opportunity to fall within any of those categories, yes, I agree. I think that's -- I think we're close here if not on the ground on top of the --

MR. REINHART: Even -- can't get there, maybe that is true.

DR. YANCY: The calculation seems to be where the rug lies. How you use volume inside that matrix and that seems, again this is Alling Yancy,

that seems where the rub is, is how you factor volume in, in that Nona Compromise.

MR. REINHART: So, but does everyone agree with the desired outcome, the different categories? I guess that's something we need to -- a basic fundamental question that needs to be answered.

MR. PRETANIK: Does anyone disagree?

COURT REPORTER: Would you state your name?

MR. PRETANIK: Steve Pretanik.

MR. CLEMANS: Certain -- Carol Foreman seemed to raise the question of whether anything that the inspectors or the plant did could affect risk and she sort of said prove that you can -- that people can do well enough in their controls to go to this lower three. In fact, the question that she raised sort of said, you know, you have to show risk assessment that proves that if you, you know, apply these controls that you really achieve a very low risk. Is that -- it's a reasonable standard question but I mean is it just, it's kind of doubting whether inspectors could be effective or a plant and then the question is, well, so where are we going?

DR. VETTER: This is Danah Vetter, NAFV, and I think that's the whole basis of HACCP though, is that -- that's the whole basis of the HACCP system is that you look at the highest risk in the plant, put in -- and then we get, you know, foodborne illness from that. I know you can't compare --

MR. CLEMANS: She must accept that but she's just saying prove, you know, if you put these controls in, you reduce the incidence of these diseases.

MR. PRETANIK: Well, you might not be able to prove that you -- reducing the incidence of diseases, but you can validate your process of verifying the process, verifying your process with your microchips.

MR. CLEMANS: Right.

MR. PRETANIK: This is where the emphasis would have to be --

MR. CLEMANS: Right.

MR. PRETANIK: -- on the micro quality of what you're turning out.

MR. CLEMANS: Right.

MR. PRETANIK: And one would hope that if

you're doing a good job here, it's going to affect the other but it's very hard to make that connect.

MR. CORBO: Tony Corbo, Food and Water Watch. I think for those of us, and I'm one of the consumer groups, have always had a problem in terms of why the Agency is moving in this direction. Are there public health objectives that the Agency is trying to -- or is this just an exercise in terms of managing their inspection workforce better? I think that is still a big question as to why we're doing this whole exercise.

MR. CLEMANS: To me, it's a no-brainer that if you're trying to reduce risk, you target risk. I don't think that need be discussed. The question is can you find -- can you target this? Are they adequately targeting this?

MR. CORBO: I think the problem that we still have is that the Agency hasn't fully articulated the public health goals.

MR. REINHART: The group agreed on the desired outcome as being looking like the model, well, it was without objection, is basically the answer

since we didn't formally vote, and then the next question becomes --

UNIDENTIFIED SPEAKER: Wait.

MR. REINHART: I'm interested in keeping to the question. The next question is are there changes that would make either of the approaches, make them more effective, and this is really relates to all of these other questions we've asked. And certainly there are opportunities to make it more effective. Everyone's said that.

The question becomes which ones do we want to say are the opportunities we would like FSIS to look at. The first one, Danah, public health outcomes, I believe that FSIS has been charged with that already. So it's not a volume question. It is an RBI question that they need to answer. I don't know if they're planning to answer it prior to these things happening or after doing their initial assessment. I don't know about that, but I know they're going to try to answer that question. So I'd like -- I mean that's an appropriate question. But related to volume specifically, what would we change

to make it more effective in this model?

Well, the compromise model did not offer an equation. So obviously if we said that's the desired outcome, an algorithm is needed to support that outcome, right? So that would make it better. Because without, we can't go forward. So I think that's something that we could -- I mean I guess. Does everybody agree that that would make it better if we had an algorithm that checked numbers?

MR. HONTZ: One thought on that, Lloyd Hontz, with GMA/FPA. And I think this is another point that everyone could agree on, and that is that the significance of volume should be greater when the plant's controls are worse, that there's more of a concern for volume when the plant is doing a poor job of risk control and therefore elevating the amount of risk, you know, to the public from the products that the plant is producing.

And if everyone did agree with that, then that argues for some type of risk control weighted factor for volume.

MR. CLEMANS: Sort of a geometric weighting.

That would more important, your volume.

DR. VETTER: Right.

MR. HONTZ: And I don't think --

MR. CLEMANS: On the downside though, that it make the bad little guys, let them off the hook.

MR. HONTZ: I don't think they ought to get off the hook. We're talking about a volume penalty or additional points they get or more inspection than they have the very littlest volume, then there really shouldn't be any penalty provided for them that ought to come into play through their establishment risk controls and that they can measure. And again it gets to how you put your algorithm together to get the desired outcomes.

And we've always said as a coalition that you never know whether the algorithm is working or not until you plug in some numbers and see if you get logical outcomes, the folks who need the most inspection actually get it with the numbering system or whatever you come up with but again, I think that that's key.

As best I can tell, the Nona Matrix which

the Agency used is going back to the original proposal which applies volume equally across the board regardless of what the risk controls are, and I think that's maybe something we could agree that is appropriate.

DR. YANCY: Alling Yancy, U.S. Poultry and Egg. One of the things that I think that I sense that we're hung up on is the discussion revolving around volume and in one of the presentations it said risk equals hazard times exposure or hazard and exposure are interrelated to each other, to come up with the risk volume. The assumption that's there, and I think it's a safe assumption, but it depends on the parameters under which you're looking at that. The assumption that's there, I don't disagree with you, Dr. Vetter, is that the product is already a double grade, and that's not a safe assumption to make when you're looking at a plant without knowing its establishment risk control, without knowing it's compliance issue. And that goes along the lines of what Lloyd was saying. If that plant has a poor performing history and your establishment risk

controls show that they are poorly performing, then that is a safer assumption to make that the product they're producing, the volume of product they're producing is more likely to have adulterant or have an issue associated with it and therefore the exposure to the consumer is more likely to be impacted. And conversely if a plant is a better performing plant, more regulatory compliant, it is equally safe to assume therefore that that product is less likely to be adulterated and therefore the exposure would be less.

So I'm not suggesting exposure and hazard combined together equal risk. I'm suggesting that we cannot make the assumption without knowing the history of the plant, the performance history, and the establishment risk measures. Without knowing that, it's not safe to assume that just because they're producing product A they fall into this category based on the volume of that product they're producing.

That's another reason why I believe the way in which we get to that calculation is where the rug lies, but I still think that volume should be

considered an issue based on performance and their risk measures that are in place. And a plant with poor risk measure controls, volume hurts them more. It weighs more, and rightly so. It should. In a plant with better risk control measures, that volume, regardless of how high or low it may be, weighs less. That's an algorithm that I could support.

DR. VETTER: Danah Vetter, NAFV. I completely -- I understand what you're saying and I can see where it actually, you know, could work that way, but I still think because where you go with inherent risk, it's species and product type. And we all know like deli products, hot dogs and so forth, is a greater risk to the public. And so if you've only got 100 hot dogs out there, then it's a low risk of people getting sick, if there's just 100. But if you've got 1 million hot dogs out there, it's a much higher risk. So I guess even if that plant is a great plant but let's say for one day, you know, they have this great risk control measures, they don't have that many NRs, but they have a malfunctioning oven, and they produced 100,000 hot dogs that day that went out

and they didn't reach lethality, or they are using alternative 1 let's say, and their post-lethality treatment didn't work or something, and then you've got that many more products out there that could potentially be adulterated.

So I guess that's where I'm coming from, and I completely agree with what you're saying and what you're saying about how well you're doing or how badly you're doing should be related and relative to how much you're putting out there and how that does increase the risk. I agree with that. But I do still think it is part of inherent risk because even in a perfect plant, something could go wrong and you have a greater amount of product and you have a greater population exposed to that than you do with the smaller establishments.

So as far as question number 2 goes, we've got some differing opinions on that. There's been suggestions about how that could be equated with your suggestion that it's a weighted volume, it counts more depending on how well or how badly you're doing, that it be part of the risk control measure versus inherent

risk. Any other -- and then that we needed a new algorithm to support that Nona Compromise, the Nona Compromise. So that everybody has the opportunity to fall in any category. Did I miss anything?

MR. REINHART: Bob Reinhart. The next question is, "What specific records should the inspectors use to approximate production volume for the various product categories in these approaches?"

DR. VETTER: This is Danah Vetter. And I've actually filled out that survey that they're talking about myself, and I do believe that it needs to be altered somewhat because I think they're low balling the numbers. I think there needs to be more categories because I think there's just a very large range of volume when we talk about establishments that are out there. So I think that more data needs to be collected as far as volume, because I think right now, what's out there right now is a very low, low estimate for some plants. I won't say for many percentage-wise, but for some plants, and I say that because they pop out around 50 something when you talk about that. And we know, those of us that are in plants,

particularly large plants, there's a lot more being produced.

My suggestion for collecting volume data is not just me when I sit down with my colleagues and discuss this, would be that the Agency uses an instrument similar to what Don talked about with RTE, that they do it for all establishments and they implement it in a very similar way that they did the RTE form which is where the inspectors gathered the information originally and then when they got OPM --

MR. CLEMANS: OMB.

DR. VETTER: OMB, thank you. When they got approval, they made an electronic form so that it was easy so that industry could fill out. They could still do the survey with the inspectors as well because then you've got two sets of data to compare. They won't be exact, but they should be close. And so you have two sets of data to compare and you take the information from the industry and they have the ability to feed that data into Excel or some sort of statistical database and then put it on a distribution curve. And then you have a score of volume based on

where you fall on that distribution curve, and it won't be normal distribution.

And I'm not a statistician, but I do -- I know a small, a tiny bit about this. I suspect you'd see something like a funny looking triangle, and then they can use that information in the algorithm and it would be a more accurate representation of volume that's out there. And then maybe it wouldn't overshadow so much when you have 1, 2, 3, 4, 5, and we have so many people just grouped into category 5. Maybe it could be more spread out that way.

MR. REINHART: Bob Reinhart, Sara Lee Corporation. I agree that I believe FSIS could go to OMB and request that companies provide this information. I do not think the burden would be extremely large. I don't know how difficult it is for policy to go generally to OMB, if it has to be through a rule or if it's just through a direct -- or how that works. But if the idea is to get more accurate and better data, certainly the company stating what their production volumes are and whatever classes you want, would be the most accurate, and I think that is

definitely something that could happen. I don't know that anybody's really going to oppose it, the Paperwork Reduction Act or whatever the requirements are, it's not going to be a huge burden on industry.

MR. CLEMANS: That would be easier to do if industry supports it.

MR. REINHART: Well, I can't --

MR. CLEMANS: If one guy complains and no one says that, you know, this association likes it, it makes it really hard.

MR. REINHART: Yeah. I don't know --

MR. PRETANIK: Do people ever really comment on --

MR. CLEMANS: Actually, yes, they do. In fact, the way it's set up now is that, as industry people you should know this, you can call directly to the OMB analyst, almost in secret, and feed them a good or a bad line, and if they believe you, it's just hell for the Agency.

MR. REINHART: So it may be a difficult process. It may be feasible at least for better data.

In the short term, I also believe and the --

was great on the PBIS information and we do try to go over that with our inspectors and understand that our PBIS information is accurate, and that is a choice of the company. It's not mandated and, you know, FSIS just -- asked for it, but it's a pretty darn good system. At least they have the information that we didn't have a few years ago. I know that questions of volume have come up in the past and now we're at 4300 establishments. We actually have a pretty good estimate. It could be off, a little low, a little high, I'm sure, but those things could be overcome by the option of going to industry to provide their data. I don't know what happens if you have to tell industry it's optional to provide your data. Then you have to go through OMB. I don't know how those intricacies, as a policy may --

MR. CLEMANS: Yeah, it's required you have to go through OMB and six months would be really -- a year would be plausible at best.

MR. REINHART: So use the current system and then potentially go to make it better. That would be my recommendation.

MR. CLEMANS: So you would be comfortable though starting with the PBIS system provided that people said they wanted to go to an industry reporting system.

MR. REINHART: Bob Reinhart. I would be comfortable with the PBIS system being used to reflect industry data. I don't have the integral knowledge of what it says but what I know is just our establishments and the volumes and the classifications of the plants when we review that with them is not far off.

MR. HONTZ: Lloyd Hontz, GMA/FPA. I just have a question about how you do get that information. You indicated you collect it, the information in the plant. How do you come up with the numbers?

DR. VETTER: Danah Vetter. It's actually quite easy if you're in a large establishment because the cutoff is relatively low compared to what is actually put out within a day. So if you're in a large establishment, that's sort of an easy thing to answer because it's usually greater than the FSIS amount that's on the survey.

If you're in a small establishment, I assume that you would talk to the plant manager or talk to maybe the HACCP manager or somebody that could help provide you an estimate. They're not necessarily, you know, required to do so, but it's kind of your best guess. You can also look at records. There are records that you can look at. They're not records that you physically look at because you're typically looking at HACCP, SSOPs, SPS records. You're looking at labeling. You're not looking at complete volume of what's going out in your daily inspection duties. So you would need to request certain records. It probably wouldn't be a bill of lading. You'd probably go to their accountant, you know, something like that, an accountant position.

The other side of that is the slaughter establishments. For the animals that we slaughter, we do get a number back for that but it doesn't account for what comes in from other plants and it -- processing plant. So it goes into our database, which is called EADRS, E A D R S. And it's also based on a calculation but it's a good estimate of that product

that was slaughtered, how much was that will go into product being produced or going into commerce.

So that is a way that we also look at it if you're in slaughter establishments. That doesn't hold true for processing establishments and it also doesn't incorporate everything that's gone out because things come in from other plants as well.

MR. HONTZ: In regard to the questions that were raised this morning about product shipped versus product produced. Do you know why it's shipped at this point in time and not produced?

DR. VETTER: Danah Vetter. I don't know why but I have an opinion. My opinion is that this should be based on product produced, not product shipped. Because product produced is the potential to go out there in commerce and who knows when, especially if it's frozen product. You know, if it's dark meat in chicken, and I talk about poultry because I'm in a poultry establishment and that's primarily what I've been trying to do, but if it was dark meat, there were times when we had trucks and trucks and trucks and trucks, and not enough room in freezers, when the

Russian export thing was going through, and it wasn't going out because the market wasn't there for it. So it can be in the period before the product is actually truly considered shipped. So I believe this should be based on product produced and not product shipped.

MR. CLEMANS: Probably the main risk with -- production.

DR. VETTER: Yes.

MR. CLEMANS: Does the industry have responsibility for anything in the freezer?

DR. VETTER: Yes, and the --

MR. CLEMANS: And make sure the temps were kept low enough --

DR. VETTER: Yes. I mean before it goes out the door, there is an inspector -- before it is shipped, there's an inspector that checks that product that makes sure that it meets certain standards, whether it be export requirements or the basic SSOP standards that USDA enforced. They're called ivy warehouses. And there is some regulatory enforcement there. Most of it pertains to the countries that they're exporting to and then their particular

requirements.

DR. YANCY: This is Dr. Yancy, Alling Yancy, U.S. Poultry and Egg. I understand what you're saying, Dr. Vetter, but I respectfully disagree. I believe it should be based on product shipped because until it enters commerce, it hasn't entered commerce. If it hasn't left the producing establishment, then it's not in commerce yet, and there are opportunities still for the plant to find and address issues of food safety or any other type of regulatory issue that may have occurred with that product before it leaves.

So the real measure should be once it's left that producing establishment and gone into commerce, not what has been produced because an excellent example of that would be, although this is probably very minimal in exposure, but an excellent example is a plant that tests, pardon me, produces and holds RTE products waiting for *Listeria* testing, and if that plant was measured based on its production by pounds of product, it would be askew, because in some cases, God help them, that plant will get back on some level, *Lm* positive results. That product will either

be condemned or it will be recooked and in recooking it, more product is lost in the recooking process. So looking only at the amount of product that's produced versus what they ship, you're going to get a skewed view of the risk to the consumer. So that --

MR. CLEMANS: If you want to interpret the risk for sure, maybe you have to look at both. I mean some people sort of ship right away and some people hold.

MR. YANCY: Some do.

MR. CLEMANS: Because I would think you'd just --

MR. YANCY: Some ship from the producing establishment to a distribution center or a freezer where it may be held before it then moves on. But in the definition, that's why I used the definition in commerce. Once it's left that producing establishment, it's in commerce.

MR. CLEMANS: Right. The question is where is the risk? Where does risk occur? More in the production or in the storage and shipping.

MR. REINHART: Bob Reinhart, Sara Lee

Corporation. I believe that this is a little bit of semantics. I believe under HACCP the issue of shipment is once -- complete, okay, this is where probably most people are looking at product as being produced and shipped. Regardless of whether or not it's literally sitting on the dock and shipping out tomorrow morning and those type things, I believe probably that is what's happening. It has been marked for inspection and -- review is completed. They're counting it in the daily production volume. I believe that's probably reality.

The simple answer to that is to spell that out in the directions to the workforce, whatever they say, I believe. I actually think we're pretty close on this. So I just wanted to note, under HACCP, -- review -- issues, as the deciding point of you produced this product and so, you don't know if the form says, no, you've got to wait until the product goes on a truck but, you know, literally if they did it at that point, it would be appropriate in my opinion.

DR. VETTER: Go ahead, Tony.

MR. CORBO: Tony Corbo, Food and Water Watch. I tend to agree with Dr. Vetter. We have a recall going on right now of year old hamburger, you know, involving 400,000 pounds that's being recalled. Probably most of it has already been consumed because it's a year old but, you know, there's an *E. coli* recall going on right now. So I would tend to agree with Dr. Vetter that it has to be produced.

You know, the other thing, and I won't use the word appalled because on April 2nd, some of the Agency folks got on my case in terms of how this information was being collected in terms of volume but I would tend to think that you would want the most accurate information possible and I'm hearing, at least from some industry representatives here, that maybe going the OMB route would be the best way to do it.

You know, if I were a plant owner, having the inspector trying to stalk around, trying to find my production, I would be very concerned. And so I think you would want the most sanitized records in terms of what volume is made available to the Agency

and doing this, this little surreptitious, you know, stalking around of records, I don't -- I feel very uncomfortable with it.

DR. VETTER: This is Danah Vetter again. I would just say that I know that the process may be very lengthy, you know, a six month period of time for something to get approved, but just like they did with the RTE instrument, it could originally be -- the form could originally be provided to inspectors who would gather that information, like they did with RTE product. And then once it gets approval, then it could go into the industry who fills it out. So -- and you follow that from notices, you know, you put a notice out to the inspectors and then they do a follow up just like we've done with the RTE form. And so if it was something very similar, it would be done so that you could have information now instead of down the road that would be a little more accurate because you could tailor the form to provide that to you in a more accurate sense than the survey provides. And then follow it up with after approval, the industry doing it.

MR. CLEMANS: Being part of the Government, I guess I should thank you. I -- your idea.

MR. REINHART: And then the last question is does anyone have other suggestions? I think it's important if somebody has them. Does everybody have a --

DR. VETTER: We have about five minutes. We have about 15 minutes. So I guess we have 10.

MR. REINHART: Right. So do you have anything, Lloyd?

MR. HONTZ: Lloyd Hontz, GMA/FPA. We've been working on something, an alternative view. It certainly hasn't been mentioned to our RBI coalition at all, but it is something that I feel comfortable throwing out on the table. Again, I want to reiterate that what we really looking for, based on Janell's presentation, is that the outcomes are reasonable to go along with the guidelines that we were talking about earlier, but one way that I think possibly could get us there is really treating inherent risk and risk control measures and volume as three independent factors although again the volume would be weighted

and based on the established risk control. But one possibility would be adding a value for an inherent risk measure to a value for RCM, risk control measure and then adding an additional factor or value for volume. Again, this volume factor would be weighted mathematically depending upon the value that you were giving for your RCM. And again, to get to the desired outcomes, you can vary the numbers as you need to.

One other possibility that this allows is -- the weighting part, the risk control measures at a higher level than the inherent risk perhaps if that gets us where we need to be. So that's one option that we're working on, and we'll do a little more with it and share it with folks and see if it gains any traction. If it does, we can certainly share it with the Agency. If not, we'd be happy for them to come up with something that gives the desired outcomes.

DR. VETTER: This is Danah Vetter again. I just want to make sure, in thinking about it in my head, I kind of like that idea a little bit that you have volume as a -- sort of factor. So that it doesn't necessarily go with inherent risk and it

doesn't necessarily go with risk control, which is where there's a disagreement between different people. And so it's actually a third factor in this equation. And I guess were you thinking of looking at that as three different numbers or like a pair, like they were talking about a pairing, that this would be a comparison of the three separate numbers or would they come together to compute one number?

MR. HONTZ: In our thinking up to this point in time, they would be three independent numbers which would be added together to get one number but the bottom line would still be a level of inspection which would be 1, 2 or 3, and perhaps that would be information made available to the public. All of these would be added together.

DR. VETTER: Any other comments on that suggestion or any other ideas that anyone has?

MR. REINHART: Bob Reinhart, Sara Lee Corporation. I'm going to make a comment and this is just in essence to make sure I do say this. The actual goal as the lone representative, the actual plant operator here in this scenario for us, as a

corporation, is to improve the public health outcome related to risk and Agency oversight. And a risk-based inspection system that focuses on those risks is beneficial in theory to that outcome but we don't necessarily get into the details or the concern over what level of inspection are you going to fall into when the game's figured out.

Actually what we want to have happen is to have a safer food supply. Then in turn, the resources and the levels of inspection are right. That's the answer to our question that we're going to eventually hopefully get to, and I just wanted to state it because I know a lot of people have mentioned incentives for companies, and I'm not against that if that is what drives a company to get a better intervention, very good. I think it's something that the Agency can offer. But I also think that's not ultimately necessarily the goal of everyone, and so I just wanted to state, you know, for Sara Lee, our goal would be a better food safety system which then falls into a better regulatory oversight system.

MR. HONTZ: Agreed.

DR. YANCY: This is Alling Yancy, U.S. Poultry and Egg Association. I think from the trade association's standpoint, I absolutely agree with everything that you just said because in looking at it I guess in from the -- we obviously want the consumer to be safe, and we obviously want the resources that the industry puts towards doing that to be effective.

So if a system is set up that's flawed, and we're evaluated by that system and it's flawed, then we're wasting resources and we're not protecting the consumers. So we want a system that's adequate and is reasonable and that's also productive and by productive I mean not just lowest common denominator, cost effective, but the biggest issue is the consumer being made more safe. Because if they're not, then all those resources, however little or however big they may be, have been wasted and in the end, the consumer is still exposed. And that's now what any of us want.

MR. REINHART: Now we're going to present when we go back I believe, and you will --

DR. VETTER: I've been taking a lot of

notes, and I'm going to try and make sure that I get both, you know, everybody's opinion out there. I don't want to say both. It's not both sides because there's a lot of different opinions between, you know, different people on the regulatory side, on the consumer side, and on the industry side. So if I miss anything or if I don't get something out there that you thought was really important, please let me know. I don't get my feelings hurt too easily. So --

MS. JOHNSON: Great. I think if we have nothing else to say, we can break before we have to go back in five minutes. Thank you.

(Whereupon, at 11:40 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

April 25, 2007

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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Andy Vogel, Reporter

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