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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CONFERENCE CALL BREAKOUT

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10:45 a.m.

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I-N-D-E-X

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

(10:45 a.m.)

DR. KAUSE: It's really important to have a common understanding of the terminology so that we're all on the same page and can provide the best input as we have a dialogue on this particular issue.

Risk is a function of both hazard and exposure. With that said, what that means is if you are -- in the case of hazard, hazard is the noun. It's the agent that's causing the illness. Exposure, in the case of food safety, is the likelihood of ingesting that particular hazard. For example, if you're consuming a food that doesn't have the hazard there, then you're not at risk. Same, if the food has the hazard present, but you don't eat that food, you are not at risk.

So in looking at the exposure side of this risk assessment equation that we normally use and is widely recognized by the National Academies of Science as well as Codex, exposure has two components to it. Exposure is both the likelihood and amount of hazard in a single serving of food. It is also the number of

servings produced. The likelihood of a hazard in a single serving of food is the per serving risk. The number of servings give us a population risk.

For risk-based inspection, it's pretty understandable that there would be a variation in the public health risk posed by the products and processes, whether we're looking at ground beef, chicken breasts or ready-to-eat meat and poultry products.

When we look at the risk associated with the products that are being produced and put out there into commerce, we're actually looking at the per serving risk, the likelihood of contamination of a serving of food. This is impacted by the product type, which has an effect on the survival and growth of a hazard in a food. We look at process, the time and temperature that would influence the growth of the hazard in food. We look at interventions which influence whether or not the hazard can be mitigated, reduced or altogether eliminated, and we have compliance data that provides actual empirical evidence of what is going on in that particular

establishment.

With that said, a large producer who produces product that has a low likelihood of contamination in his product may be less risky than one that's smaller and has a lower production volume but it has a higher likelihood of contamination. It's the likelihood of contamination that actually is driving the risk. The volume is there to adjust that to give us an idea of how much hazard is being introduced into the marketplace and consumed by our consumers.

What I'm asking folks here today to think about is, the debate is not whether or not we should use production volume. The -- has to use production volume, is an integral part of assessing risk. The question really is how do you appropriately and scientifically weight production volume so that it's used in a way that measures population risk without overwhelming the likelihood of contamination thinking?

MR. TYNAN: Thank you, Janell. And I'm going to ask Dr. Engeljohn to give you his 50 cent version of his earlier presentation.

DR. ENGELJOHN: Thank you. I'm Daniel Engeljohn with the Office of Policy, and I gave an overview about how we, the Agency, currently collect information within the establishments relative to volumes. I gave an overview about the OMB approval process in which we seek approval from OMB through the 1995 Paperwork Reduction Act process, in which we itemize what it is that we need from industry, why we need it, who all is affected, how much time it would take to collect the information and then provide regular updates to OMB as to a justification as to why we need to continue collecting information in this way.

One issue with the OMB approval is that it is something that the Agency has traditionally not been successful in getting approval to survey establishments regarding various activities simply because we do have inspectors in every establishment who would be able to make general or relative estimates about the types of information that we are seeking.

I gave the overview about the OMB approval

for the *Listeria monocytogenes* regulation that we have in place in which through the regulation, we sought approval to have OMB approval to collect specific information about the production process and the effectiveness of the interventions used to control *Listeria* in very specific exposed post-lethality product. That approval process is one for which we have to get re-approval each year, and the industry is required by regulation to provide us some very specific information.

As an alternative to that, the Agency is able to use the scheduling process through our performance-based inspection system to ask questions of the inspector with regards to filling out the establishment profile related to types of products produced and the amount of products produced. And we did that in December. We asked questions about 19 product categories, and these categories can be modified at anytime. At that time we had a need amongst the Office of Policy, the Office of Food Defense, the Office of Public Health Science and the Office of International Affairs, to collect specific

information about a variety of products for a number of different activities within the Agency including risk-based inspection.

Those 19 categories of products, we ask the inspector to identify whether or not the products were produced, how much was produced and we gave ranges for the inspector to make a selection from in order to parse out the aggregate differences that may occur in the establishment. And then we asked them to make that estimate of approximately poundage over the course of the last 30 days.

This would be the type of thing that the Agency would expect the inspector to update at anytime in which substantial changes occur within the production practices of the establishment. And for purposes of the Agency, this type of information is sufficient for purposes of making general estimates.

And then I gave an overview about our response rate which was 96 percent of the establishments, the inspectors in those establishments did submit a response, which we think is an extremely high response rate from most surveys of this type that

we ask of the inspection force.

We did quality control in that if there were questions or inconsistencies in the answers, we had a group of individuals who followed up with the district managers and with the inspectors in those operations, to clarify the responses that were given.

And then I just provided an overview about the differences between the HACCP size category in terms of production volume. The larger plants do, in fact, produce the most amount of product, and that we have a fairly large number, 14 percent of the establishments produce multiple, in this case, more than five different types of the products on that category listing.

And so that was the overview that I gave. I made it clear that this kind of information is more than sufficient for purposes of making general estimates, and then provided some overview about how we can use that information in the future. Thank you.

MR. TYNAN: Again, I want to apologize for the folks that are on the phone for the delay and the technical glitch we had earlier this morning and for

getting you on the conference call.

I mentioned to the group earlier that Mr. Schad had offered to be the Chairperson of this group and, Mark, are you there?

MR. SCHAD: Yes, I am, Robert.

MR. TYNAN: Okay. Mark, I think you indicated that you were going to be able to handle the conference call with the help of the Operator. Do you need any assistance from us?

MR. SCHAD: No, I don't believe so. Just for the benefit of everybody else, I do have an open line. So I'll be able to speak up at anytime, and I'm going to be taking notes on my end. Do I have a note taker there, Robert?

MR. TYNAN: We can get one for you if you'd like.

MR. SCHAD: It might be good if possible. If not, I can do without. If we had another note taker, it might be good.

MR. TYNAN: Okay. We'll get a note taker in to make sure that we double up and again, you have until about 11:45 Eastern.

MR. SCHAD: Okay.

MR. TYNAN: And again, I appreciate you doing this for us, and I'll turn it over to you and get a note taker in the meantime.

MR. SCHAD: Okay.

MR. TYNAN: So we're going to leave you live so that we can hear your discussion here. Everyone has gone to another room, but I'm afraid if we turn the sound down, we may lose you again, and I don't want that to happen. So we're going to keep you on line.

MR. SCHAD: Okay. And for the people on the call here, as Robert said, we have a limited amount of time. So we have four questions. So I'm really going to have the clock on us, so we don't run over on each question, and if I cut in, I want everybody to have an opportunity to make their comments, but if you talk for what I believe is a little bit too long, like I said, I want everybody to have an opportunity. So if I cut in and ask you to kind of finish up your comment so we can move onto somebody else, I apologize up front. I don't mean to be impolite, but I do want to

give everybody the opportunity and I think it would be good if we got through all the questions.

So with that, Operator, I am ready and we'll do question one, of course, to start out with, and that is "What are the advantages and disadvantages of each approach?" That being as far as the previous one, as of April 2nd of three levels or the one presented by Don Anderson today, the Nona Matrix Approach.

OPERATOR: And all lines are muted. So if anyone has a question or comment, they will need to press *1. Otherwise, if you'd like me to, I can open all the lines at this time. Would you like to just take questions one at a time, sir, or open all lines so everyone --

MR. SCHAD: Let's just take them one at a time.

OPERATOR: Okay.

MR. SCHAD: I'd like them to identify themselves and their affiliation.

OPERATOR: Okay. Carol Tucker-Foreman, your line is open.

MS. TUCKER-FOREMAN: Thank you very much. I have a question of Dan, and that is, do you have the OMB approved instrument kind of data for anything other than your nine types of RTE products? Do you have -- is all of your data on raw ground beef from the PBIS extension?

MR. SCHAD: Dan, are you there?

(No response.)

MR. SCHAD: Carol, maybe Dan is not there.

MR. TYNAN: I'm sorry. Dan has gone. I apologize. Janell was calling your attention -- I thought you were having your dialogue. No, Dan has gone to one of the breakout rooms here and is going to be wondering around. Is there a question or perhaps something that we can --

MR. SCHAD: Carol had a question for Dan. Apparently he's not there. So the question was, is there an OMB instrument other than for the nine RTE products?

MR. TYNAN: Okay. Maybe we have somebody else who can answer it.

MR. SCHAD: If not, we'll just move along to

the next person who wants to make a comment.

DR. KAUSE: Hi, Carol. Actually here's Dan. He can answer that.

MR. SCHAD: Okay.

DR. KAUSE: Dan, you received a question --

DR. ENGELJOHN: The OMB survey -- this is Dan Engeljohn. The OMB survey is one for which we ask for specific approval from OMB, and we actually go through the Federal Register to make it known that we're going to collect the information. We identify all the parameters of what we're asking and why we're asking it, and how many people are affected, how long it will take to complete the survey. And then there's an opportunity for the public to comment on whether or not the survey can be enhanced or improved or modified or to give stakeholders the opportunity to express their opinion about FSIS collecting the information.

So that's a very formal process that we go through the Federal Register to get public input. And we, for purposes of collecting volume information, really the only specific OMB approval that we have presently is one which is directly related to 9 Code

of Federal Regulations, Section 430, which deals with post-lethality exposed ready-to-eat products. And, it asks questions about the various types of deli meats and other ready-to-eat products. It asks which alternative for the *Listeria* control is used, how frequently the establishment conducts environmental food contact and product sampling, and it asks questions about the intervention and level of effectiveness.

We have to go through each year to get re-approval of that and industry is required to submit information on an annual basis.

We do not have approval from OMB to collect the same kind of information on any other process, and that is why we use the inspectors-in-charge in every establishment that's regulated to make general estimates about the types of products. And so ground beef and beef manufacturing trim were 1 category of the 19 that were asked about in our December production volume profile extension survey. I hope that answers the question.

MS. TUCKER-FOREMAN: Thank you.

MR. SCHAD: Thank you, Dan. And if we could, let's make our comments to specifically start to answer each question please.

OPERATOR: Ron Fouche, your line is open.

MR. FOUCHE: My question was really of Dan. He used a figure of 14 percent for multi-products within the companies. That was a little surprising to me. I'll touch base with Dan later. It's not really important today. I don't have another comment at this time. Thank you.

OPERATOR: Barbara Kowalcyk, your line is open.

MS. KOWALCYK: I have a quick question for Dan. I know you said that we don't have OMB approval for other products, but is FSIS looking to get more OMB approval to collect the type of data that it needs to determine volume for RBI?

DR. ENGELJOHN: This is Dan Engeljohn, and I think I heard that question which was are we going to seek approval for OMB for the type of information that we need for RBI? And as I tried to make clear in the presentation, the OMB approval process is a multiple

month and in some cases a year long or longer effort to get the information after we have justified why we have to ask industry to provide that information as opposed to collecting general information that we can get through our inspection force. And by regulation, the *Listeria* rule is the only production process recordkeeping approval that we have that's specific to production volume. That's the only one that we have been able to get approval for. So that's the reason why we use the PBIS profile extension for other information for which approximations are sufficient.

MS. KOWALCYK: Okay. I'm just a little concerned because the inspectors are strapped, you know, basically as it is and -- I think it would probably be useful to maybe look down the road to getting that type of approval. I know it's timely and difficult -- meantime but, you know, getting better data.

OPERATOR: Thank you. Patricia Buck, your line is open.

MS. BUCK: This is Pat Buck from Center for Foodborne Illness, Research and Prevention. And my

question is a little more general because I'm looking at the whole model and one of my questions would be is there going to be some type of linkage between the industry or FSIS testing program to what we're doing with volume. In other words, will there be a method in our risk-based inspection formula that will allow when a negative test result for whatever product it is comes back, you know, for whatever pathogen, will we then have a method by which we can say, whoa, we have a problem here and we need to weight the volume a little heavier. And since I didn't hear all of the, you know, conversations that were going on with the presentations, I don't know if that was kind of addressed?

MR. TYNAN: Excuse me. Can I interrupt? This is Robert Tynan, and I was moderating the meeting earlier. I just want to remind everybody that we're supposed to be focusing specifically on the questions. I know there are some things that you need to have clarified.

MS. BUCK: Yeah.

MR. TYNAN: Dan needs to go around to the

other sections. So for all of you, and to help Mark out so that he has something to report, come 45 minutes from now, that we focus on the questions, the advantages and disadvantages. And if there are issues --

MS. BUCK: You're absolutely right, and that would be if we don't have that brought in, that would be a disadvantage of what we have --

MR. SCHAD: Okay. Barb, I'm sorry, I mean Pat. Will you restate that disadvantage and then we'll get that down.

MS. BUCK: What my concern is, is that does this program have any linkage between the industry or FSIS testing program for whether it's *Listeria*, *E. coli* or *Salmonella*, okay.

MR. SCHAD: Okay.

MS. BUCK: And if we don't have a linkage between that data and how we are applying, you know, our weight to volume, should we put one in place? Because I think we should and I think that perhaps that has to be clarified.

MR. SCHAD: Okay. Thanks, Pat. I think

that's a good point, and for the benefit of everybody here, let's just say I have, this is an advantage or this is a disadvantage to each approach here, and then we're going to have to move along here or we'll never get done.

OPERATOR: Lamar Hendricks, your line is open.

MR. HENDRICKS: Thank you. Mark, good morning. I have a question or a comment rather on raw meat and that is in the calculation of assessing risk, the volume was for practice considered that raw meat is ultimately cooked and when you're taking about per serving basis, is that factor considered when you look at volume that goes out of a plant versus the fact that there's a yield off? I don't know whether that's an advantage or disadvantage but --

MR. SCHAD: Okay. But I believe I understand what you're saying, Lamar, and I think that's a good point. So thank you for that. Did you have something else, Lamar?

MR. HENDRICKS: Not right now, Mark.

MR. SCHAD: Okay.

OPERATOR: Once again, *1, if anyone has a disadvantage or an advantage please.

MR. SCHAD: Okay. I'm going to jump in here with a comment. I kind of like the Nona Approach because I always -- when I was looking at it, I thought that was a lot more descriptive of describing a plant. When we talk about this Level 1, Level 2 and Level 3, Level 3 can mean a lot of things. Is it a plant that's making a high-risk product or is it a plant that has poor risk control measures? There's always going to be -- if we do it that way, we're always going to have a vague sense of what's going on. So that is my comment as far as an advantage on the Nona Matrix.

OPERATOR: Someone has queued up. Ken Mastracchio, your line is open.

MR. MASTRACCHIO: Yes. Hi, good morning. I was hoping to be there this morning but unfortunately some other issues arose but thanks for having me on the teleconference.

One of the things that I wanted to bring up was the advantages I believe to risk-based inspection.

I think it would lend more toward a more consistent and uniform type of a verification of the food process systems that we have and maybe relieve some of the subjectivity that we have that kind of leaps in from the old traditional command and control type of inspection. And I believe that would be a tremendous advantage.

I'd also like to state, too, my support for and with Joe Harris and his discussion today on volume, as volume should be calculated in regards to a plant's ability to control their process and not have it linked to inherent risk. Thank you very much.

MR. SCHAD: Okay. Thank you. I think in the interest of time, unless there's some more comments for question number 1, let's move to question 2, which is "Are there changes that you would make to each approach to make it more effective?"

OPERATOR: Sir, we had a few parties queue up from the prior question.

MR. SCHAD: Okay. That's fine.

OPERATOR: Ron, your line is open.

MR. FOUCHE: Thank you. I liked -- sort of

liked Joe's approach quite frankly to it. I think the advantage there, although the algorithms themselves may not make a lot of sense to most people, I think Joe's approach to it makes a lot more sense. The, I wouldn't say flexibility but the ability to have more variety in there seems to make more sense at that point for both the large and the small. And obviously the very first one was that they -- being in April, was poor at best. And I think this is a much better -- Joe's is a much better approach at this time. Thank you.

MR. SCHAD: Thanks, Ron.

OPERATOR: Barbara Kowalcyk, your line is open.

MS. KOWALCYK: Yeah, I guess because I missed out earlier, I'm not clear what Joe's approach is, but the question I have, I guess comment is last fall there was a lot of talk at the public meeting both from industry and consumer groups about having volume as a third axis, and I was just wondering what had happened to that discussion.

Not only that, you know, FSIS is trying to

do a data driven system, and I'm a little concerned, I just caught the tail end of Don Anderson's comments, concerning the -- you know, that they were changing the algorithm almost daily, and that certainly implied that they're not using the data to drive this and I was wondering about that. And so I don't know exactly what Joe's algorithm is and maybe I'm confusing something else, but I think that, you know, using volume as a third axis makes a lot more sense than putting it in product inherent risk.

MR. SCHAD: Barb, this is Mark. Would you say that would be something we could fit in as far as a response to question number 2?

MS. KOWALCYK: Yes.

MR. SCHAD: Okay. Thank you.

OPERATOR: Once again, *1 if anyone has an answer to the question.

(No response.)

MR. SCHAD: Any comments for either question 1 or 2?

OPERATOR: Once again *1 at this time.

MS. JOHNSON: Mark?

MR. SCHAD: Yes. Hello.

MS. JOHNSON: Yeah, this is Sheila. I'm in the room. I'm supposed to be taking notes.

MR. SCHAD: Yeah.

MS. JOHNSON: Were you going to tell me at what point you wanted me to write down anything or are we going to do that as you wrap up?

MR. SCHAD: As we wrap up, Sheila.

MS. JOHNSON: Okay. Thanks.

MR. SCHAD: Thank you.

OPERATOR: No one has pressed *1, sir.

MR. SCHAD: Okay. Thank you. Let's move onto question 3 and that is, "What specific records should the inspectors use to approximate production volume for the various product categories in these approaches?"

OPERATOR: Ken Mastracchio, your line is open.

MR. MASTRACCHIO: Yeah, hi, Mark. In regards to question number 2 with changes, I know a comment was made earlier about, you know, this algorithm seems to be changing all the time but as far

as an approach though, the one concern I had was with the algorithm that it be as simple and as transparent as possible. I guess that's more of a comment, but like I say, if this thing keeps on changing, as we meet each time, and that's not a bad thing. I think it's getting more refined and it's getting better as we get more input. Thank you.

MR. SCHAD: Okay. Yes, thank you.

OPERATOR: Once again, *1 to answer the question.

MR. SCHAD: Any comments on question number 3?

OPERATOR: Carol Tucker-Foreman, your line is open. Carol, please press your mute button.

MS. TUCKER-FOREMAN: I'm sorry. I assume you're dealing with question 3 now?

MR. SCHAD: Yes, Carol, that's correct. This is Mark.

MS. TUCKER-FOREMAN: I have a concern, and I think it was expressed as well by Barbara Kowalcyk, that it's hard to have a data driven system when you don't have data, the inspectors have a very hard time

conducting all of the activities they're supposed to conduct now and I don't believe that the data that they collect under the best of circumstances is the best data that you could have on something for example as important as ground beef. What we need, in fact, is instead of relying on the inspectors to provide this information, FSIS needs to have this information from the plant directly on a continuing basis. I know that's hard to get but you're talking about the safety of our food, and we continue to have a problem when FSIS says it's too hard for us to get the data that we need. So we're going to use the data that we have. We just don't think that's acceptable.

MR. SCHAD: Thanks, Carol, and I'm going to jump in and make my comment now and I seem to agree with you on this one, Carol, because I don't see anything wrong with getting verification from the plant management on the production volume. I think that can only help and not hurt. Maybe an inspector would want to do his PBIS extension and put down what he believes to be the production volume, but I see nothing wrong with him going to plant management and

saying this is what I've got down, can you verify this figures for me and thanks for that.

OPERATOR: Ron, your line is open.

MR. FOUCHE: Thank you. I think again John indicated that 96 percent they had a response from. Now I know what happened in our facility and I know what happened in quite a few of the facilities I'm aware of. The inspectors don't know the first thing about production for all practical purposes. So I wonder where they get it from? They get it from the plant, and I can't help our friends at the political side, at OMB, in what they want to do, we get too dang much paper as it is today, but this is one of the things that I happen to agree with Carol, this particular point, that, you know, the information can be gotten.

Quite frankly, in all due regard, the inspectors are not that busy. They can do it. They can sit down with management. If management just decides not to share that information, that's a different story. They really can't do anything about it but I don't know of anybody that's not willing to

share, if nothing else, the approximate amount, the technical side as well, what do you make, what do you ship? Well, that's almost irrelevant. You're going to make whatever you have a -- of the product, a little shrinkage, that's not it. We're looking at approximate pounds and I think that information is all available and if this is going to help us in such a way, in my opinion, that industry would not support this type of thing if all we on the association side would say, hey, give them the help, give them the help if they need it. Thank you.

MR. SCHAD: Thank you, Ron, and I'm going to just say this. It seems like we had three people here agree on something. Can somebody jump in if they disagree with that? If not, maybe we can come to a consensus on this question.

OPERATOR: Barbara, your line is open.

MS. KOWALCYK: I actually jumped in. I don't disagree. I actually agree, and I think, Mark, I believe it was you who suggested that having done in a way with the inspector's report, when if at all possible, the plant would report it to FSIS, I think

that's an excellent idea because I feel that it's basically following a control validation type technique that FSIS could then go ahead and try to verify the data and how accurate the data is. If they get different estimations from the plant versus the inspectors, that might raise a question as to whether or not the inspector has a good idea of what's going on, whether it was a typo or so forth.

So I think that that's an excellent idea. Sorry I jumped in when you wanted someone to disagree but I agree completely. Thanks.

MR. SCHAD: Thanks, Barb.

OPERATOR: Ms. Sharbach, your line is open.

MS. SHARBACH: Yes, I sort of jumped on before. I concur with what's going on with this assessment. I think the question I wanted to pose if we are finished with this though, is the question was what are the specific records, you know, should inspectors use to assess the volume or what do we think are those records?

And I again go back to this list that was put out by the, you know, exposure, the product

support, the survival and growth of the pathogen. Are these the types of things we should be talking about, the interventions? Is that whole program, the testing? Because I think when they look or think about volume, some of the recordkeeping that needs to be maintained are the things that would cause them to, you know, say that volume is important because of the problems with exposures, and that would be pathogens. So are these part of the records we should, you know, be addressing in this question is my question?

MR. SCHAD: Okay. Thank you. I don't know if someone is in the room who can answer your question or not. Maybe we can just move on and get that answer later.

OPERATOR: Barbara Kowalcyk, your line is open. Barbara, your line is open.

MS. KOWALCYK: Sorry. I think Pat brought up a good point, and that is you need to first of all define what you mean by volume. Okay. It's pretty clear to me from looking -- that volume could be interpreted different ways. So when they start looking at data, I was told that FSIS -- agreed upon

definition of volume means, what's shipped, what's moved, you know, -- thanks.

MR. SCHAD: Okay. I just want to make sure I'm clear on this, Barb. So you're getting at the specific records we should look at.

MS. KOWALCYK: Right. And you need to have -- you can't just say to the plant, tell me how much volume, you know, how much product you move. You need to actually sit down and define what you mean by volume because it's pretty clear to me that, you know, somebody might interpret volume as what was shipped, you know, is it an aggregate over a period of time? Is it, you know, a medium? Are you talking about the average for a 30-day period? What are you talking about specifically? You want everybody on the same page because otherwise your data analysis could be skewed.

So, you know, it just seems to me listening to people talk here today that -- I certainly don't remember the gentleman who spoke earlier. He raised it up, you know, is it the pre-cooked weight or, you know, the post-cooked weight. I think that was one of

the points he brought up. Is that correct?

MR. SCHAD: Yeah, Barb. This is Mark, and I think that was a point he was bringing up, and to make sure I capture your thought here correctly, you're talking about as far as the records be consistent and actually have some parameters set.

MS. KOWALCYK: Well, you have to define volume, you know, what do you mean by volume? So that when you ask Plant A and they give you an answer and they're listing volume to be what was produced, and Plant B is interpreting it what was shipped and Plant C interpreted it as what is the cooked weight or whatever we talked about. Because then when you go to analyze the data, it's really not -- right. And so, you know, sometimes when you have a lot of confusion over a definition, it's simple. You just come up with a definition and say we're talking about volume, this is what we mean, and then collect the data based on that definition. It will be helpful for inspectors as well because, you know, it'll give everybody, you know, you're giving your best estimate based on this specific definition of volume.

MR. SCHAD: Yeah, Barb, I think that's a point well taken and just from my personal experience, a lot of guys you'll ask, well, how much are you producing and they tell you how many combos they bought that week. So I think it's a point well made.

MS. KOWALCYK: Right. In terms of -- I just don't want to see FSIS go off and start collecting data and really they have to sit down and think about the nitty-gritty of what they're collecting. I mean age is a perfect example. How do you calculate age? Some people take today's date minus the birth date as age. Some people take today's date minus the birth date plus 1 as age. You know, people can calculate things differently, and it might be insignificant but it might be significant when it comes to doing the data analysis involved and everybody's not on the same page.

MR. SCHAD: Absolutely, Barb.

MS. KOWALCYK: All right. Thank you.

MR. SCHAD: Thank you.

OPERATOR: The next question comes Ken Mastracchio. Your line is open.

MR. MASTRACCHIO: Yeah. Hi, Mark. Maybe I've been in this industry a little too long, but about 20 years ago, the Agency used to collect what they called and MP404 which was a weekly production and in that sheet, there was product categories and plant management would enter in the volumes of those product categories and that would get handed into the inspector. And in turn, that would go to Headquarters I don't know exactly what they did with that but there was that system in place at that time.

MR. SCHAD: Yeah, I do remember that, Ken. So thanks for your comment. So I don't know if that's something we could go back to or not, whether it's something that the form is still approved or not. So thank you for that.

MR. MASTRACCHIO: Okay.

OPERATOR: Our next question comes from Patricia Buck.

MS. BUCK: Hello. This is Pat Buck again, and while I agree 100 percent with, you know, what Barbara was talking about as to identifying volume, what I was trying to get more to is getting back a

little further in the how do we -- what type of assurances will this Nona Matrix have for showing if there is any difficulties with the product. In other words, something has changed. They found a test result or a new intervention has been put in place that would lower risk. Is this volume matrix going to be able to incorporate that so that we can, you know, make the change? It's not clear to me and maybe it's because I didn't hear the whole presentation, but I don't understand how we're going to be able to get to use this in a flexible model. And I don't know if that's as a result of, you know, the specific records that we should be keeping on it.

I mean is it important for the microbiological testing, whether it's done by FSIS or by industry. Does that information, will it have an impact on how we are going to be weighting volume for that, you know, for that particular establishment when it's discovered? Just like if the establishment puts in a brand new intervention, how are we going to go about incorporating these two to adjust the volume? Does that make sense to anybody out there?

MR. SCHAD: Pat, this is Mark. I understand your question. I don't know the answer to it. I guess yesterday was the first time I looked at this Nona Matrix and I don't know whether they know how the algorithm would affect the Nona Matrix. I don't know. Does somebody else want to make a comment on that?

(No response.)

MR. SCHAD: Okay. This is Mark again. I think that's maybe a question if everybody is okay with that, we can pose or put that down as a comment somehow in the report. Here's another suggestion. We can put it in as a disadvantage, Pat. I'm just going to ask you that question.

MS. BUCK: Well, yes, I think if we do not have something put into the discussion about volume about how we are going to take those items that are important and inherent product risk and process the, you know, control, if we can't have some method by which we can identify that now is the time that volume is going to carry more weight because they've just put a new intervention in place, and we need to make sure that this intervention is working properly. Do you

see what I mean?

MR. SCHAD: I know what you're saying, Pat.

MS. BUCK: Yeah. So I see it, it may be a disadvantage. On the other hand, because I didn't hear the totality of the report, maybe that's already figured in there in which case, you know, it doesn't -- in which case they're already considering it. But I think that one thing that has to absolutely be defined along with the things that Barbara commented about, is what are those product records or what are those items like intervention or testing or where the product is going or, you know, is this -- we found a pathogen. We only found a small amount of it, but it's a multi-drug resistant one. So we're going to be a little more hyper about that one, than one that we are maybe not so concerned about. You see what I'm saying? We have to have those identifiers from the isolates, so that we know what's going on with these various pathogens to be used to help us determine whether or not we need to put more weight to volume.

MR. SCHAD: Okay. We're going to put that

down as a comment, Pat.

MS. BUCK: Okay.

OPERATOR: Patricia, does that conclude your question?

MS. BUCK: Yes, I'm finished.

OPERATOR: Okay. Thank you. Carol Tucker-Foreman, your line is open.

MS. TUCKER-FOREMAN: I'm sorry. I will pass on this one. I do have a comment when we get to question 4.

MR. SCHAD: Okay. Thanks, Carol.

OPERATOR: Ron Fouche, your line is open.

MR. FOUCHE: I think Pat in all due regards is mixing her metaphor. I don't know where an intervention factor has a volume unless you would see how much you could shove through a particular piece of equipment or whatever an intervention would be.

When we look at the risk factor, we're looking at, you know, what can the company do? The company can control volume. The company cannot control the inherent risk within a particular item that they might buy in, such as whether it's pork or

beef or whatever it's going to be and what they're going to do with it. But the volume side of it, I don't particularly -- I don't know if we want to go back to it. I think that's why OMB got rid of it because of all the paperwork that was required of us many years ago, like some of you have been in the business a long time. But to ask the question on occasion as to what are you doing, how much are you doing, I don't see any company in the industry, maybe some of the big guys may have a problem with that, but I think most of we small or very small people, it's a simple question we can answer off a hand. If somebody wants to exact pounds and ounces and talk about shrinkage and this kind of thing, that's a real challenge, and that doesn't really stand a place in the overall picture of volume in that. So I think it should be used, the nine figure. I think it could work. You've got to give it a chance I think. Thank you.

MR. SCHAD: Okay. Thanks, Ron.

OPERATOR: Our next question comes from Lamar Hendricks.

MR. HENDRICKS: Mark, this is Lamar Hendricks, and I did have a comment about the control or the risk control for changes to the matrix. As I understood it, I thought FSIS indicated that they would change the ranking possibly monthly so changes would take effect. As far as new interventions, I think those new interventions have to be validated through the HACCP control program.

MR. SCHAD: Yeah, I would tend to agree with what you just said, Lamar. I don't know if anybody else has a comment on that.

OPERATOR: Lamar, does that complete your question?

MR. HENDRICKS: Yes, that's it.

OPERATOR: Okay. Thank you. Joel Poesa (ph.), your line is open.

MR. POESA: Thank you. I just wanted to make -- coming back to the volume thing in general, and some of the comments I've heard made, I think we need to go on with that to what Janell was saying and top off, you know, the risk of exposure and what not. So the only volume that should be of concern to us is

that to which the consumer is exposed, that is, you know, product that's actually moved in commerce.

So if you start talking about what's made what shift -- what's put in cold storage, what's released. The only thing that counts is what constitutes an exposure. So that might -- that's just a comment that I -- with.

Based on that volume, you can't really use in-plant inspection records, you know, going back to question 3, what records can inspectors use. I'm not sure that in order to do this properly, the inspectors can produce that information. That goes back to Carol Tucker-Foreman's comment about the collections pool and OMB pool. Now I know that USDA, the stockyards -- out and, you know, it's Congressionally mandated and it's a regular thing. Those are types of things I think that you're going to have to start addressing here to get a volume measure that's going to make sense in terms of a risk assessment decision. So I don't really -- per se. I'm just making an observation and I think in terms of volume in any case, you have to address those things in order to get

a measurement that makes sense within risk assessment. That's it.

MR. SCHAD: This is Mark. I'm sorry. I did not catch your name.

MR. POESA: I'm sorry. It's Joel Poesa. I'm a farmer for Eckridge Meat.

MR. SCHAD: Okay. And so you're -- I'm not trying to put words in your mouth. I'm just trying to capture your comment. Are you saying that the volume figure should come from plant management?

MR. POESA: Well, I think it's going to have to come from somewhere within the -- frankly, your volume is going to have to be revenue based, but if every company knows how much volume they make and we all know because that's how we make money. So, you know, anything that enters into commerce is, we gain a revenue from. That's where you're going to have to dig to get a -- and then you take all this issue of yield and shrinkage and everything out of the -- and that's your point of exposure.

MR. SCHAD: Yeah. Okay. Thank you. I appreciate that.

MR. TYNAN: Excuse me. Mark, I just wanted to give you sort of your 15-minute warning.

MR. SCHAD: Yeah, okay. I appreciate that, Robert.

MR. TYNAN: Okay. Thank you.

MR. SCHAD: I was curious how close we were. For the people on the phone, I wanted to make one comment here about records or changes maybe, if I can group questions 2 and 3 together here. If I remember correctly from the April 2nd meeting, the Agency was talking about collecting volume annually. And in my opinion, to me that was not often enough, and the first thing that came to mind because those of us in the industry know that a lot of products, most products are seasonal. And so that in and of itself will have a lot do with the volume. And those of you who know my operation, making just hams, you know, at Christmastime, my volume is relatively high and then in January and February it's relatively low. So doing it on an annual basis may not be the way of doing that. That's my comment on that.

In the interest of time, if we could jump

down to question 4. So that is, "Do you have other suggestions for how to factor in exposure into assessing the risk presented by an establishment?" And then maybe after about maybe 7 or 8 or 9 minutes of comment, then we'll have to maybe wrap this up somehow so I can make a presentation. Thanks.

OPERATOR: If you have a question, press *1. We have a question from Carol Tucker-Foreman.

MS. TUCKER-FOREMAN: Thank you. I have -- I'm not sure that I understand question 4 because it talks about factoring in exposure and part of this may be again that we didn't get to hear all of the presentations. But I thought we were talking about volume, and Janell's slide show showed two forms of exposure, exposure as the characteristic to a product and exposure as to the volume of the product. So it seems to me that we ought to try to be very specific that we're really talking here about volume only.

And I specifically I think that it's important because although FSIS makes assumptions that controlling interventions and inspection reduces the number of foodborne illnesses, we don't really have

any data to show that they do. We've got some assumptions that in my view increasingly are stretched. CDC said all these *E. coli* interventions have not reduced the level of *E. coli* in over a decade. We have to take that into consideration. So I think it's important that we talk specifically here today about volume rather than the particular risk characteristics. And if I'm completely misunderstanding that slide number on -- I think it's the fourth or fifth slide, it's called risk-based inspection, I need to know.

MR. SCHAD: Yeah, this is Mark and, Carol, I think we need suggestion -- we're having a meeting here on volume and there is nothing wrong with changing the question if we need to. So I'm the Chairperson and I'm going to stick my neck out and say let's change the question so it's based on volume.

OPERATOR: I'm showing no further comments.

MR. SCHAD: Okay. Thank you, Operator. Are there any other comments or questions in general that anybody would like to make?

OPERATOR: Mr. Mastracchio, your line is

open.

MR. MASTRACCHIO: Yeah, Mark, yeah, just a comment in regards to, you know, the calculation of volume that it also consider a plant's microbial interventions.

MR. SCHAD: Okay. Thanks.

MR. MASTRACCHIO: Okay.

OPERATOR: Carol Tucker-Foreman, your line is open.

MS. TUCKER-FOREMAN: I think I'm seeing part of the problem here now is that I think the industry's proposal is that volume be altered, the impact to volume be altered according to the interventions that have been taken. And I, I don't think that we've addressed that very much in our discussions of these particular points. The questions don't seem to go to that. And I want to take us back to the beginning and say that I would still think that it's useful to deal with volume as a third axis in this and try not to -- and to leave the effectiveness of intervention in as relevant to product inherent risk. I've already stated my concerns about whether we really know how

important that is. I acknowledge that's all the plants can do but my concern is more generally about what FSIS is trying to do when we don't have that basic information. And to come back to it, I think that my bottom line out of all of this is an even stronger feeling that we should deal with volume as a third axis. Thank you.

MR. SCHAD: Thanks, Carol. I just want to make sure I captured that. That would be like the answer to question number 2, are the changes that you would make to each approach to make it more effective. Is that correct, Carol?

MS. TUCKER-FOREMAN: Yeah. Yes, it is, and I think it was suggested by several people or by a couple of people at least earlier and I just want to go back and add my voice to that.

MR. SCHAD: Yeah, okay. Yeah. Thank you, Carol.

OPERATOR: Patricia Buck, your line is open.

MS. BUCK: Yes, this is Pat Buck, and I didn't hear all of Carol's statement but I do concur and that's what I was going to say, is that I think

volume is probably a -- what I would call a living, breathing thing that is part of production. It's extremely important, and I think that to address that, we probably need to use that third axis. All right. So I actually -- that's what I was calling lastly to say.

Other factors that we may want to consider might be things within the Government that are giving weight of importance, like the CDC FoodNet data. I think we need to, you know, seriously look at some of these other, you know, findings from other Governmental agencies about the food system, and they're not going to have an impact, of course, just on volume, but they would certainly have an impact on our whole approach to risk-based inspection, and I think that's very, very important to take what we do know from the different agencies, different perspectives and bring them together so that we can impact on how we are, you know, developing risk-based inspection. That's more of a general comment. That's all. Thank you.

MR. SCHAD: Thanks, Pat.

OPERATOR: Heather Rolla, your line is open. Heather Rolla, your line is open. Please tap your mute button. Heather, are you able to hear us?

MS. ROLLA: Yes, I can hear you. Can you hear me?

OPERATOR: Yes, now we can.

MS. ROLLA: Sorry. I am from the west part of North Dakota, a teeny tiny little town, and I just have a couple of comments.

First, I want to concur with what Carol said earlier about volume data, but I also have to agree what she said about interventions being used. Like I said, we're a small plant, and if we're going to take into account microbial interventions that are used, we might be penalizing the small and very small establishments because these interventions are extremely costly. And I think that only the larger establishments are going to be the ones that are going to be able to benefit from those.

And also I'm a microbiologist at heart, and I have a concern about some comments that were made about using microbial testing data, FSIS or industry

or otherwise. Only a small amount of finished product is tested, and unless we've got data that tells us that there's a baseline level for each microbe on the products, I don't know how we could consider that data in the algorithm. I don't think that it's really something that should be taken into consideration. If we do 100 tests and all those tests come up negative, that doesn't mean -- that tomorrow I'm going to have a positive. But I just think that we need to be careful with that, but overall I think that FSIS is doing an extremely good job. We don't have necessarily the same kind of concerns with shortages and inspectors up here, but I think that all of the volume data, at least annual our inspectors come to us and ask us approximately per month how much product you produce and we gladly give them that information. We like to have an ongoing communication with our inspectors where everything can flow smoothly. So that's kind of my general comment on everything. Thank you.

MR. SCHAD: Thank you. Operator, how many people do we have queued up right now?

OPERATOR: Two.

MR. SCHAD: If those people could be very quick, because I want to do a little bit of wrap up here.

OPERATOR: Lamar Hendricks, your line is open.

MR. HENDRICKS: Thank you. Mark, I believe and I don't mean to be disagreeable, but I think that risk -- I don't think volume needs to be part of the inherent risk axis. I think it is a risk control measure. So in other words, it should be moved to the other axis and furthermore, I believe that volume is not necessarily a bad thing because what you do in volume is, for example, if you make hams all day, you're very familiar with that process and everything's set, it's in place, and you're running.

However, if you change product 15 times a day, you stand a chance to have more risks interjected in those product changeovers, through sanitation efforts, through equipment changeovers, et cetera. So I don't think it needs to be part of inherent risk. I think it needs to go to the risk control measure and so that's my comment.

And the other thing as far as specific records, or changes to each approach, I think the major changes need to be based on plant history of compliance, intervention, and these things are not going to automatically move from one category to another. They're going to slowly move. So it's not something that's going to happen immediately unless there's an outbreak or a for cause problem.

So those are my comments. Thank you.

MS. JOHNSON: Mark --

MR. HENDRICKS: Yes.

MS. JOHNSON: -- this is Sheila. We have people beginning to wander back in the room just to let you know where we are.

OPERATOR: Barbara Kowalcyk, your line is open.

MS. KOWALCYK: I'll be very brief, Mark. Basically I just wanted to reiterate that volume be the third axis. Also I wanted to comment on, you know, collecting volume data and -- I don't know what sort of time it would be, but I would think -- . Also something that has not been talked about, and it may

have changed since it changed in the algorithm, is how are they going to define, how are they going to test -- how are they actually going to use it in the algorithm? I know in the algorithm that was presented on April 2nd, they were going to take volume and actually rank plants -- the top 20 percent of the producing plants get a five, the second 20 percent would get a four and so forth, and my only comment on that is -- FSIS before is that volume is actually food distribution where you have a lot of plants using a little bit of product and a few plants a lot of product and so that's skewed distribution and basically by percentile separates plants out -- uniform distribution -- you know, that need to be addressed and -- even talked about how they're going to actually compute volume and use it to define plant -- risk and that leverage.

MR. SCHAD: Okay. Thanks, Barb. And, Sheila, are you there?

MS. JOHNSON: Yes, I'm here.

MR. SCHAD: Okay. I assume people are walking in. I won't have time to wrap up with the

people on the phone.

Is that correct?

MS. JOHNSON: Yes.

MR. SCHAD: Okay. If it's okay with the people on the phone, I'm just going to by myself put my notes together in a presentable way and go ahead and present it. And then after my presentation, if anybody has any comments or questions, maybe I didn't reflect what was said during our conference meeting here, you can do it at that time.

So if I say anything is not correct, I'm going to apologize right up front and thank you for all your comments. I know this wasn't the easiest way of having a committee meeting, but thank you all, and I appreciate it.

MS. JOHNSON: Mark, this is Sheila again. Would you want to be the last to report? That will give you a chance to write your notes up.

MR. SCHAD: I appreciate that, Sheila.

MS. JOHNSON: Say that again?

MR. SCHAD: Yes.

MS. JOHNSON: Okay. I'll let Robert know.

MR. SCHAD: Okay.

(Whereupon, at 11:45 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

CONFERENCE CALL 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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DOMINICO QUATTROCIOCCHI, Reporter

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