UNITED STATES DEPARTMENT OF AGRICULTURE

FOOD SAFETY AND INSPECTION SERVICE

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In the matter of: *
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NATIONAL ADVISORY COMMITTEE *
ON MEAT AND POULTRY INSPECTION *
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Via WebEx

Thursday,
September 24, 2020

The above-entitled matter came on for hearing, pursuant to notice, at 9:30 a.m.

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VALERIE GREEN
APRIL REGONLINSKI

A P P E A R A N C E S

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I N D E X

P R O C E E D I N G S

(9:41 a.m.)

AUTOMATED RECORDING: Your line is now unmuted.

AT&T EVENT PRODUCER: Welcome and thank you for joining today's conference, the National Advisory Committee on Meat and Poultry Inspection Public Meeting. Before we begin, please make sure you open a member's chat panel by using the associated icon looking at the bottom of your screen. If you require technical assistance, please send a chat to the event producer.

To submit a written question, select All Panelists from the dropdown menu in the chat panel, type your question in the message box and send.

With that I will turn the call over to Valerie Green, moderator and Designated Federal Officer for the Committee. Valerie, please go ahead.

MS. GREEN: Thank you. Good morning, everyone. My name is Valerie Green and I'm with the Office of Policy and Program Development within the Food Safety Inspection Service. I'm the Designated Federal Official for the National Advisory Committee on Meat and Poultry Inspections and I will also be

serving as the moderator today and tomorrow.

It's my pleasure to introduce the Under Secretary of Food Safety, Dr. Mindy Brashears, who will give the welcome and opening remarks.

Dr. Brashears?

DR. BRASHEARS: Thank you so much. Good morning, everyone. I am Dr. Mindy Brashears and I am the USDA's Under Secretary for Food Safety and the NACMPI Chair. I want to welcome all of you to our virtual NACMPI meeting. As always, I wish we were all sitting at the table together but I am thankful and grateful we can get together in a virtual setting and, hopefully, one day we will be sitting together face to face.

This is our first meeting of the Committee since 2016 and I'm really excited about what you have accomplished over the next couple of days. There are some specific issues we are going to ask the Committee to evaluate and address at the meeting. However, before we get started on that I want to remind everyone of the important role that NACMPI's Committee plays in food safety.

NACMPI was established almost 50 years ago, in 1971, and six years prior to the creation of what is now known as FSIS.

The role of the Committee is to advise the Secretary of Agriculture on food safety concerns and policies that will contribute to USDA's regulatory policy development. The Committee should be balanced in terms of the point of view represented, geographical representation and food safety interests and as you look at the Committee members you'll see members with a wide range of expertise and various backgrounds.

I want to encourage you to listen to one another and to consider other points of view as you make your -- as you contemplate the questions we've put before you.

Recently, we announced the appointment of the final two members of the Committee. All 20 members bring a multitude of perspectives from the industry, academia and the public sector. I want to thank all our members for their contributions. Each of you bring a unique expertise, experience and viewpoint to this forum.

This Committee which provides science-based advice on the inspection of FSIS-regulated products, helps ensure that our regulatory system is relying upon the latest evidence. We are also counting on your expert knowledge of food safety to advise on

how FSIS should apply the latest science to our regulatory systems. Now we can move on to our specific issues to be addressed at this meeting.

Over the course of the next two days we will listen to relevant updates from Agency officials and comments from the public. We will also charge the Committee with deliberating and providing recommendations on two important issues.

First, FSIS is seeking guidance on what steps the Agency should take to ensure better control of artisanal shelf-stable, ready-to-eat, fermented, salt-cured or dried products that rely on multiple hurdles for lethality. This is an opportunity for the Committee to deliberate on how the Agency should react when it determines an establishment lacks scientific support for their lethality treatment.

We also want you to consider how we can better assist the industry in gathering the necessary data to support lethality treatments.

Second, FSIS would like the Committee to advise whether the Agency should continue to not test boxed beef primal and sub-primal products for Shiga toxin-producing E. coli, also known as STEC, if they are intended for intact cuts. We know that

processors located downstream are often unaware of the producers' intended intact use or the risks of grinding these particular products.

We look forward to your recommendations on best practices for sampling and testing so we can reduce STEC-positive outbreaks, recalls and deaths. These are two equally important matters and in the interest of time and discussion the Committee will divide into two subcommittees, one to evaluate each issue.

Each subcommittee will provide a report of their comments and recommendations to the full Committee before the meeting concludes tomorrow.

As you deliberate in your subcommittee remember the important role you play in food safety. Your insight and remarks may shape regulatory policy and impact public health for years to come. Not only do we encourage and appreciate your feedback, we depend upon it.

I look forward to what this Committee can achieve over the next two days. With the breadth of expertise gathered in this meeting, I am confident that we will advance the Agency's efforts in food safety policies to further protect public health.

Now, it's time to get to work and thank you

so much for your time. I will turn it back to our moderator.

MS. GREEN: Thank you, Dr. Brashears. Next slide, please.

I'd like to briefly review the agenda for today. We'll start with the Agency Updates. As Dr. Brashears mentioned earlier, this is the first meeting of the Committee since 2016 and today we want to update from the charges presented at that last meeting. We will then move forward to the 2020 NACMPI charges. Next slide. And after lunch, the Committee will be divided into subcommittees to address the charges.

There is a slight change in the schedule today. We did not receive any requests for public comments so we will extend the deliberation period to 4:45 p.m. and at that time we will reconvene for the day's wrap up. Next slide.

Now, let's turn to the introduction of the Committee members. Next slide.

We're going to go in order in which they appear on the slide. Before we begin, I would like to inform everyone to please state your name and affiliation for the official record before you speak or ask a question for the duration of the meeting.

Now, let's start with Mr. Gremillion. Mr. Gremillion --

MR. GREMILLION: I'm sorry.

MS. GREEN: Okay.

MR. GREMILLION: This Thomas Gremillion, Director of Food Policy, Consumer Federation of America.

MS. GREEN: Mr. Jenkins? Okay. Mr. Jenkins is the Director of the Louisiana Egg Commission.

AT&T EVENT PRODUCER: Looks like Mr. Jenkins is on the attendee line. Your line is now unmuted. Please go ahead.

MR. JENKINS: This is Jim Jenkins. I'm the Director of the Louisiana Egg Commission for the Department of Agriculture and Forestry.

MS. GREEN: Dr. De Mello?

DR. DE MELLO: My name is Amilton De Mello, Meat, Science and Food Safety Advisor for the University of Nevada in Reno and the State Specialist for Meat, Science and Food Safety.

MS. GREEN: Next slide.

MS. RENDON: Hi. This is Tina Rendon. I do Food Safety and Quality Assurance for Pilgrim's Pride Corporation.

MS. RICE: Kim Rice, Vice President of Food Safety and Quality for Rose Acre Farms.

MS. GREEN: Dr. Avery?

AT&T EVENT PRODUCER: Dr. Avery, if you have joined the attendee line can you please press #2 so that I can unmute your line? Dr. Avery, your line is unmuted. Please go ahead.

DR. AVERY: This is Jimmy Avery. I'm Extension Professor and Extension Aquaculture Leader with Mississippi State University. I'm also currently serving as President of the World Aquaculture Society.

MS. GREEN: Next slide. William Battle?

AT&T EVENT PRODUCER: William, your line is now unmuted. Please go ahead.

MR. BATTLE: I'm Bill Battle, Tunica, Mississippi, owner of Pride of the Pond Catfish, Battle Fish Farms.

MS. CONKLIN: This is Tina Conklin. I am the Associate Director of the Michigan State University Product Center and the Director of our Food Processing and Innovation Center.

MS. CURTIS: Hi. This is Pat Curtis. I'm the Department Head for the Prestige Department of Poultry Science at North Carolina State University.

DR. EBERLY: Hi. I'm Jennifer Eberly. I'm the State Director for Maine's Meat and Poultry Inspection Program.

MS. GALLIMORE: Casey Gallimore, Director of Scientific and Regulatory Affairs at the North American Meat Institute.

DR. HARRIS: Joe Harris, President of the Southwest Meat Association.

AT&T EVENT PRODUCER: Dr. Lynn Knipe, if you're on this attendee line please press #2 so that I can unmute your line. Your line is now unmuted. Please go ahead. Dr. Knipe, please unmute your device. Dr. Knipe, we're still not able to hear you. Can you please unmute your device?

MS. GREEN: Well, Dr. Lynn Knipe is the Extension Processed Meats Specialist and Associate Professor of Food Science and Technology, Animal Sciences at Ohio State University. We'll go on. Dr. Byron Williams.

DR. WILLIAMS: Hi. Good morning. I'm Byron Williams the Associate Extension Professor with the Department of Food Science, Nutrition and Health Promotion at Mississippi State University. I serve as the State Processing Specialist for all muscle food products including Food Safety,

Regulatory and Processing.

DR. WILLIAMS: Hi. Sherri Williams with JBS USA Food Company and I'm the head of Technical Services for our Regional Beef Division.

AT&T EVENT PRODUCER: Gregory Gunthorp, if you're on this attendee line please press #2.

MR. GUNTHORP: Hello. Greg Gunthorp, a farmer and a USDA inspected processing plant owner of pigs and poultry in Northeast LaGrange, Indiana.

MS. GREEN: And Dr. Alice Johnson, she is the Vice President of Food Safety and Animal Care with Butterball and, unfortunately, she's not able to be with us to make the meeting today. Denise Perry?

AT&T EVENT PRODUCER: Denise, please press #2 if you're on the attendee line. I do not see her on the attendee line.

MS. GREEN: Okay. Dr. Denise Perry the Food Safety and Handling and Regulatory Manager at Lorentz, Incorporated. Sarah Sorscher?

MS. SORSCHER: Good morning. I'm -- this is Sarah Sorscher. I'm the Deputy Director of Regulatory Affairs at Center for Science in the Public Interest.

MS. GREEN: And Teresa Schwartz. She's

retired. She was with the Center for Foodborne Illness Research and Prevention and she's not able to make the meeting today, as well.

And that concludes our introductions so thank you all. Oops, one more person.

Last but not least. I would like to introduce an Ex-Officio member of the Committee, Dr. Misha Robyn. She's from the U.S. Centers for Disease Control and Prevention. Dr. Robyn, would you like to say a few words?

DR. ROBYN: Yes, everybody. Good morning. Thank you. I'm Misha Robyn and I'm the lead for the Prevention and Evaluation Activities within the Outbreak Response and Prevention Branch at CDC which is in the division that covers foodborne illnesses -- thank you.

MS. GREEN: That concludes our introductions. Before we begin with the Agency Updates, I would like to inform the audience and Committee members that we will take questions after each presenter. To ask a question please use the chat function. Type your name, affiliation and your question and I'll present your question to the speaker. Next slide.

I'd like to introduce Kristina Barlow.

She'll be discussing the Agency's response to NACMPI's recommendation for controlling Listeria monocytogenes (Lm) in retail delicatessens. Kristina?

DR. BARLOW: Hello. Good morning, everyone. So as part of this presentation I'll be giving you a little bit of background about the charge that we presented to NACMPI in 2016, as well as FSIS's response to the charge and then the methodology that we used to respond to the charge.

So as part of our response to the charge we performed a focus group study so I'll be presenting the focus group questions that we used, as well as the results of the focus group study and then our next steps moving forward. Next slide, please.

So FSIS presented the Best Practice Guidance for Controlling Listeria monocytogenes (Lm) in Retail Delicatessens charge to NACMPI in March of 2016.

NACMPI recommended that FSIS coordinate outreach and enhance communication on retail best practices with our public health partners in the retail industry, state and local health departments and academic cooperative extension specialists. So the purpose of this was to ensure that our outreach

on Listeria at retail is practical, easily understandable and available to all audiences. The Committee also recommended that we collaborate with our public health partners on any updates to the Food Code that we would recommend. Next slide, please.

So in response to the NACMPI recommendations, FSIS developed an interagency Listeria Working Group to coordinate and enhance our communicated material. We also performed focus group studies to determine if the information was practical, easily understandable and available to all audiences. We also assessed the focus group study results to determine if changes are needed to the Food Code.

And so as part of our original presentation we provided information from the surveillance that FSIS performs at retail. This surveillance is performed by our investigators in our Compliance Investigation Division to go out to retail delis to perform outreach regarding our recommendations and our best practices, guidelines for retail delis and they also determine whether retailers are following the recommendations and the guidelines to control Listeria.

So as part of the outreach they hand out materials, which I'll be talking about on a later slide, and so we performed the focus group studies to determine the utility of those materials that are handed out.

So based on these focus group findings we plan to coordinate with our public health partners, revise our guidance and outreach materials and engage with industry associations and others to review and distribute the information.

We do not plan to recommend Food Code changes at this time because our surveillance data shows that a high percentage of retailers are following our FSIS recommendations which is really good news. Moving on to the next slide.

So part of the methodology for performing the focus groups, as I said previously, we performed them to determine the effectiveness of our guidance materials and any other information that we provide and so we performed the focus groups using the following -- I'm sorry. The focus groups were composed of the following major groups. We had 12 participants across large, retail groups, 54 participants from state and local agriculture departments and one focus group with five academic

participants consisting of cooperative extension specialists familiar in the retail area. The focus groups were recorded with participants' permission and this effort was approved by Office of Management and Budget and announced in a Federal Register Notice.

The focus groups were connected virtually allowing for the simulation of an in-person experience so they were performed using webinars and people were able to get the same feeling as if they were together in a room to be able to provide feedback about their experiences using FSIS and other outreach information. Next slide, please.

So I'll also mention that we do have a handout that provides additional detailed information about the focus group methodology and the study results so we'll be making that handout available on our website.

So the first question that we asked as part of the focus groups was about the distribution and availability of communication material. So we asked about how and through what format participants receive food safety information.

The second group of questions narrowed down to Lm-specific communication content. We asked the

participants about the type, clarity, quality, usefulness and consistency of the food safety information that they had received.

And the last group of questions focused in on FSIS-specific Lm communication tools. So we asked whether participants had ever seen FSIS's Lm-specific documents including the Retail Lm Guidelines and Lm Brochure and the Lm Self-Assessment Tool and from what source they received that information. Next slide.

So the results of the focus group studies we broke down by the type of participant, state and local participants, the retailers and the academics.

So for the state and local participants they received the information mainly from federal agencies including CDC, FSIS and FDA and the most sourced formats of communication were websites, webinars and training as where they received the materials.

For the retailers, they received information from federal agencies, state or local agencies and industry associations, specifically the Food Marketing Institute or FMI.

Both the state and local participants and the retail participants indicated that they prefer

email distribution and web updates of information rather than written documents or brochures that are handed out. So that just told us at the Agency that we need to focus more on electronic formats with information and less on, you know, handing out brochures or having written documents. So that's something that we'll look at moving forward.

The academics stated that they work with both the large and small retailers implying that they could be a conduit to these groups. So moving forward we plan to work more with our cooperative and state and extension specialists to be able to distribute the material as well as other industry associations such as FMI and AFDO to be able to distribute information and review it before we put it out to retailers and others. Next slide, please.

So moving on to the Lm-specific communication results, the state and local participants stated that the style of messaging was slightly different depending on what agency had provided the outreach materials, FSIS, FDA or CDC. Therefore, we're planning to work with our public health partners to make sure we harmonize our information that we're providing.

They also recommended tailoring some of the

information to inspectors and other information to retailers. So we will hit that, as well.

The retail groups indicated that FSIS's materials were clear for corporate participants but not necessarily for frontline deli operators. So an example of that that we discussed could have been that for, example, FSIS recommends using antimicrobial agents and products formulated with antimicrobial -- and that is information that could be useful for corporate participants who are ordering the products to be used in the deli but not necessarily for the person who's operating the slicer within the deli. The person operating the slicer may be more interested, for example, with specific information on how to clean the slicer and what are the steps to breaking down the slicer to be able to clean it to address Listeria.

So those are some of the ideas that we're working through to increase the utility of our materials.

The retailers also recommended that FSIS work with trade associations such as FMI to distribute the outreach materials so they reach a wider audience.

The academic participants recommended first

establishing a foundation of minimum sanitation requirements of the Food Code and then addressing Lm. So they recommended increasing awareness of Food Code requirements and teaching about the specific recommendations that are in the Food Code and then focusing in drilling down to the Lm recommendations. So that's another recommendation that we'll take into account working with our public health partner, primarily the FDA, to look at the Food Code recommendations and then addressing Lm specifically and how it fits into the Food Code. Next slide.

So that's looking specifically at the materials that FSIS hands out and distributes. The state and local health departments indicated that they need materials that are simple to understand and that they can easily distribute to retailers. Several mentioned having more visually-based materials such as posters that could be hung up in a break room. So that's something that we'll take into account ensuring that we include pictures and more easily understandable materials.

Retailers also recommended that FSIS build relationships and communication channels with state and local regulators. They mentioned that the state

and local and retail participants were not aware of the retail Lm brochure that we're currently handing out. And so we're looking at our distribution channels and working on additional relationships that we can build with the state and local regulators and the retail industry groups and others, as I mentioned, so that we can build that network to be able to further distribute our materials and make sure that people are aware of Listeria control recommendations.

The academics indicated that the Lm brochure and the Self-Assessment Tool could be improved by simplifying the format and adding more visuals. So as I said earlier, that's something that we'll continue to work on. Next slide.

So next steps, we plan to update the Retail Lm Guideline to serve as a guidance document to improve the consistency, clarity and overall content. We plan to update it with pictures and images, as suggested by the focus group participants. We also plan to simplify our recommendations to increase clarity.

We plan to coordinate with our public health partners, the CDC and FDA, to harmonize our outreach to be more consistent with the content that

has been developed by other groups and agencies. We also plan to work more closely with groups such as FMI, AFDO, cooperative extension specialists and others to review and distribute our materials. And as I mentioned at the beginning of this presentation, we also have a handout which has additional information about all of this as well as the next steps that we plan to use moving forward.

We also have a retail website that I don't have on this slide but it's in the handout and so to find it you would be able to search retail guidance, not retail guidelines but retail guidance, on the FSIS website and I will bring you right to that retail web page where we plan to post most of our materials and will be posting additional materials there at that website moving forward.

So by making these changes in our outreach materials and the way that we provide outreach materials we hope to help ensure that our guidelines are useful to retailers and we can drive adoption of food safety practices moving forward. Next slide and I'll take questions.

MS. GREEN: Thank you, Kristi. To ask a question, please use the chat function. Type your name, affiliation and your question and I'll present

your question to the speaker. I don't see any questions so we'll move on. Next slide.

MS. EDELSTEIN: Actually, there is a question that just appeared.

MS. GREEN: Okay. Thank you. This question is from Dr. Eberly in Maine. Can you tell us why the focus groups were conducted?

DR. BARLOW: Hello. Yes, we did perform the focus groups to evaluate the usefulness and the clarity of FSIS outreach materials that we're providing to retail delis. That was one of the recommendations from the previous NACMPI Committee, that we evaluate the usefulness of our outreach materials to make sure that they were useful to retailers and then use this information to further revise our materials moving forward so that we can ensure that -- better ensure that retailers are following the recommendations that control -- delis.

MS. GREEN: Thank you. And when were the focus groups conducted?

MS. BARLOW: The focus groups were conducted in July and August of 2019, so relatively recently, and we have this information now to be able to present to the Committee.

MS. GREEN: Thank you. Are there any other

questions? Okay. We'll move on.

Next is Rosalyn Murphy-Jenkins and Sally Jones. They will be discussing the Agency's response to NACMPI's recommendations on labeling features for certain processed not ready-to-eat meat and poultry products.

MS. MURPHY-JENKINS: Thank you, Val. Good morning, everyone. As Val mentioned, my name is Rosalyn Murphy-Jenkins. Sally Jones and I will provide you with an update on the 2016 report and recommendations on the Consideration of Mandatory Labeling Features for Certain Processed Not-Ready-to-Eat Meat and Poultry Products. Next slide.

First, I will briefly provide a short summary of the 2016 presentation to give context to the recommendations -- the three recommendations from the Committee, and Sally Jones will continue with the information on focus group research studies on safe handling instructions and further work that will be done in this area on safe handling instructions and manufacturer cooking instructions. Next slide.

The 2016 NACMPI presentation began with the differences between ready-to-eat and not-ready-to-eat products. Some standards of identity in the

regulation require that products be ready-to-eat, like hot dogs or bologna. For other products consumers generally expect them to be ready to eat, such as pâté. However, there are products that can be both ready-to-eat and not-ready-to-eat based on how the manufacturer chooses to market their products.

For example, if a plant chooses to classify a ready-to-eat product as not-ready-to-eat, for example a product like meatballs and sauce, they must provide assurance for either manufacturing, sanitation practices and validated cooking instructions that the product will be safe for consumption.

Thus, the label must clearly indicate to consumers that the product is not-ready-to-eat and must be fully cooked prior to eating. Such labeling features include a statement on the principal display panel, that the product needs to be cooked, cooked thoroughly or cook and serve, share safe handling instructions if the meat or poultry portion is raw or partially cooked, have nutrition information based on the ready-to-cook reference amount and cooking instructions. Those cooking instructions should not be misleading and should

adequately reflect -- related to the proper use, cooking and handling of the product.

As we explained previously at NACMPI so in 2010 FSIS contracted out to conduct consumer focus groups to evaluate several things including consumer understanding of several labeling features regarding the safe handling of meat, poultry and egg products, preparation instructions, prepared but not-ready-to-eat meat and poultry products and safe cooking temperatures for raw meat.

The findings were that consumers were increasingly relying on prepared meat and poultry products because they are convenient, quick and easy. At that time there were several foodborne illness outbreaks which suggested that some consumers were not properly preparing these foods to ensure the products were safe to eat.

Based on that consumer research there was confusion about whether the prepared frozen meat and poultry products were ready-to-eat or not-ready-to-eat. The participants in the study did not distinguish between different products and brands. Some participants considered all frozen items to be ready-to-eat and thus, not-ready-to-eat products may not be prepared properly.

Also intriguing was that most participants did not know the wattage of their microwave and thus, did not make adjustments for cooking times. They did not use a meat thermometer, but instead relied on past experiences and that they were confused about the purpose of the rest time.

Also included in the NACMPI 2016 presentation was a discussion on the Salmonella outbreak-related recall for products that were uncooked. The recalled products included uncooked breaded, stuffed poultry products, poultry pot pies and uncooked frozen poultry products.

Thus, FSIS presented charges to NACMPI in 2016 based on the recalls mentioned, as well as the fact that there are no specific regulations that require a manufacturer to label a product as raw, uncooked, not-ready-to-eat or other such features.

The next two slides include information about the three charges and the recommendations of the Committee. Next slide.

This was the first charge. Should FSIS require statements such as raw, uncooked or ready to cook and labeled as raw products that may appear ready-to-eat to convey that these products are not-ready-to-eat?

The Committee believes that a mandatory statement should be used to differentiate these products. The Committee stated that changes to required labeling should be based on the findings from the 2010 focus group work on the previous slide.

The Committee also stated the industry should conduct a new focus group study to understand the optimal messaging and design of packaging to ensure consumers properly understood that not-ready-to-eat products need to be cooked for lethality.

They suggested that the focus group design should determine what messages such as raw, uncooked, ready to cook, raw-must cook to X degrees Fahrenheit or raw-must cook to X degrees Fahrenheit for safety, would have the desired impact.

The focus groups should also utilize open-ended questions. For example, what information on this package would help you understand that this product is raw and needs to be cooked or what information on the package makes you think that the product is ready-to-eat and not raw?

In addition, the focus groups should evaluate the effectiveness of standardized locations of these statements on labels. For example,

evaluate placement and features in the top left corner and evaluate various color options, fonts and other display options to determine what best stands out to consumers.

Lastly, the Agency should use the focus groups to evaluate how best to convey rest times and it's purpose to consumers as well as evaluate the effect of finished product vignettes pictured on the label. Next slide.

The second charge was should FSIS require that such products bear validated cooking instructions? If so, aside from (a) the method of cooking, (b) endpoint temperatures of 165 degrees Fahrenheit, (c) instructions that the endpoint temperature is measured by use of a thermometer, what other information is needed?

The Committee agreed the validated cooking instructions should be required for these products. The validated cooking instructions should include the method of cooking, the endpoint temperature for safety and instructions that the endpoint temperature is measured by a thermometer.

In addition to that information, the Committee recommended that the cooking instructions should include a disclaimer to not use a microwave,

if applicable, that labels should include the appropriate method for taking product temperature and that the instructions should make it clear to consumers which steps should be followed for safety. Next slide.

And the last charge was, are there other steps that FSIS should consider requiring to prevent illness involving these products? The Committee recommended the following.

FSIS should develop a risk assessment to determine the risk of these types of products and the Agency should work with other agencies like FDA. The Committee also stated that the Agency should continue to educate consumers on food safety issues. As part of this, the Agency should develop messaging that focuses on issues related to this topic to include emphasizing reading the label, knowing your label, owning a meat thermometer, knowing how to use the thermometer, knowing how to use your appliances, like calibrating your oven.

They also recommended that the Agency should continue to work with partners including extension agencies and the partnerships made for disseminating messages. The Agency should ensure alignment with FDA for like-product labeling

requirements. Also, the Agency should continue partnering with FDA and the retail industry on how best to -- products -- possible confusion between ready-to-eat and the raw, not-ready-to-eat products.

I will now turn the presentation to Sally Jones to continue. Next slide.

MS. JONES: Thank you, Ros. Good morning. FSIS has contracted with research groups -- with a research group to do a number of focus group studies over the years. There has been a multi-year set of studies going on -- safe handling instructions should be modified and updated to better inform consumers about how to use -- how to safety handle meat and poultry products. A part of the study also included research on not-ready-to-eat products and how consumers could best differentiate between not-ready-to-eat products and ready-to-eat products.

Part of this portion of the study included collecting data through an eye tracking study to identify where consumers were placing their major focus regarding handling and cooking of products. Did they focus on safe handling instructions or on the manufacturer's cooking instructions? The study is wrapping up and the findings of the research will be forthcoming this fall. Next slide, please.

FSIS conducted a more specific study looking specifically at the handling of frozen food products in the home. Results from this study indicate how difficult it is for most consumers to differentiate between the ready-to-eat and not-ready-to-eat frozen foods. In fact, nearly a quarter of the participants attempting to prepare -- were not sure if products were raw or fully cooked, despite checking the existing labeling of the product.

An additional problem identified was the lack of proper hand washing during the handling and preparation of these frozen foods which can lead to cross contamination and foodborne illness. These issues are important to address in future consumer education and potential rulemaking. Next slide.

From the initial research on safe handling instructions, the Agency determined that additional focus group studies were needed to study consumer understanding and usage of the manufacturers' cooking instructions. The study will assist the Agency in determining the most effective channels to increase public awareness of foodborne illness and how to safely handle meat and poultry products.

We want to understand how consumers use the

manufacturers' cooking instructions for products that are ready-to-eat and those that are not-ready-to-eat. The outcome of this study will assist in determining whether revisions or additions are needed for mandatory labeling features to ensure that consumers safely handle and prepare meat and poultry products. Next slide.

On October 6, FSIS is hosting a virtual meeting on Food Safety: Consumer Outreach and Education for Today and for the Future. A number of government representatives and other organizations will be speaking at the meeting, as well as individuals that have signed up to be speakers.

FSIS plans to use the findings from the focus group studies and consumer outreach meetings to inform potential rulemaking to differentiate the labeling of not-ready-to-eat versus ready-to-eat meat and poultry products. Such information will also be critical in the development of improved consumer education information and for FSIS coordinating with other agencies in the outreach programs to approve the safe handling and cooking of -- foodborne illness. Next slide. Questions?

MS. GREEN: Thank you, Rosalyn and Sally. As a reminder, to ask a question please use the chat

function. Type your name, affiliation and your question and I'll present your question to the speakers.

Also, as a reminder to our panelists or speakers, please mute your line until you're speaking.

I don't see any questions coming up. So at this time we'll take a 15-minute break --

MS. EDELSTEIN: Val. Val. We did just a question.

MS. GREEN: Oh, I see it. Okay. This is from Thomas Gremillion. Did the focus groups consider packages with the word raw printed on them? Could you elaborate a bit on what they saw?

MS. JONES: Okay. This is Sally Jones. I don't -- we're still conducting or I don't believe we've actually started conducting the last group of focus group studies that are going to be on the ready-to-eat versus not-ready-to-eat foods and I'm not exactly certain whether that is going to be one of the things that will be studied. It's a question that we should be able to answer in the future. I certainly will bring it up with the folks in -- that are running the focus group study.

MS. GREEN: Thank you, Sally. Are there

any other questions? We'll wait a few more seconds because I realize that it may take a while to type in your question. And if there are any questions from Kristina Barlow's presentation you may type that in, as well. All right. Seeing none but if you do in the future, at least during the meeting, if you have a question for any of the speakers from the Agency Updates, feel free to type that in and we'll present it to the speakers.

So at this time I would like to take a break and we will meet back up at 10:45.

(Off the record at 10.32 a.m.)

(On the record at 10:45 a.m.)

AT&T EVENT PRODUCER: Your line is now unmuted.

MS. GREEN: This concludes the Agency Updates and now we'll begin with the charges for the Committee.

This session is open to verbal and written questions at the end of each presentation. To ask a question, please press #2 or hash tag 2, state your name and affiliation for the official record before you ask a question. You may also type your question in the chat feature and I'll present your question to the speaker. Next slide.

Meryl Silverman will present the first charge regarding the validation of ready-to-eat shelf-stable products that rely on multiple hurdles for lethality. I'll go ahead and turn it over to Ms. Silverman.

MS. SILVERMAN: Thank you, Val. Next slide, please.

So as Val indicated, today I'm going to be presenting on the first charge related to validation of ready-to-eat shelf-stable multi-hurdle lethality products. Today I'm going to be giving you an overview of the issue including the lethality charges recommended safe for products, the validation challenges that we see related to research staff and then the questions for the NACMPI Committee. Next slide, please.

There is an increasing interest in producing artisanal/niche self-stable ready-to-eat fermented, salt-cured and dried products that rely on multiple hurdles for lethality. These are products such as salami, prosciutto -- and -- there's a lot of information on how to produce products of high quality but not as much available supportable science on how to produce safe products.

For example, FSIS is routinely asked about

scientific support available for -- and has only recently one single study available that supports critical operational parameters that result in a 5.0-log reduction in Salmonella and --

Currently, very little scientific support is available for establishments to use to support the production of these multi-hurdle products. FSIS is in the process of developing guidance for these processes but the lack of scientific support may raise enforcement questions that FSIS is going to need to address. Next slide, please.

FSIS considers all ready-to-eat products to be adulterated if they contain pathogens of public health concern depending on the type and level or their toxins that can cause illness in humans. There are some pathogens where any level would make the product adulterated such as Salmonella, Listeria monocytogenes or Lm and Shiga toxin-producing Escherichia coli or STEC or S. aureus enterotoxin because the presence of these types of enterotoxins would be injurious to health under the Acts.

In addition, 9 CFR 430.1, also known as the Listeria Rule, defines ready-to-eat products as those that are edible without further preparation to achieve safety.

So these ready-to-eat shelf-stable fermented salt-cured and dried products are required to be free from Salmonella, Lm, STEC and S. aureus enterotoxin at the end of the lethality treatment and also Lm should be addressed for fatality. Next slide, please.

So in order to support products that are not adulterated under the Act, establishments are required to design the HACCP system to meet all applicable performance standards or charges. And so products such as those that are dried, fermented or salt-cured, FSIS recommends the process achieve at least a 5.0-log reduction in Salmonella in order to support the product is ready to eat.

Establishments may also validate for STEC such as E. coli O157:H7 as well as Listeria monocytogenes because these pathogens are more tolerant to acid and drying than Salmonella. However, we have accepted research with Salmonella alone, provided there's no indication such as test results that the process is insufficient in addressing STEC or Lm. The research has supported that a 5.0-log reduction in Salmonella is sufficient for shelf-stable products. Indeed, the FSIS risk assessment of the impact of lethality standards on

salmonellosis from ready-to-eat meat and poultry products found that there was not a significant increase in cases of salmonellosis if turkey and other shelf-stable meats and poultry products achieve 5.0-log reduction instead of a 7.0-log.

Establishments also have the ability to support alternative lethalities provided they provide an equivalent probability that no Salmonella organisms present in the finished product. I'm going to discuss this concept further in a few slides.

FSIS also recommends ensuring S. aureus outgrowth is limited to two logs or less during processing to ensure no enterotoxin production.

For the purposes of the NACMPI charge, though, where we see the research gaps are related to supporting the 5.0-log reduction of Salmonella and other pathogens. Next slide, please.

So I'm going to share some examples of where industry has come together to develop scientific support related to the lethality of multi-hurdle lethality products and the limitations of these documents that have resulted in continued research gaps.

In 1994, an outbreak of E. coli O157:H7 was

linked to commercially distributed, dry-cured salami. In response, the Blue Ribbon Task Force on E. coli O157:H7 at the National Cattlemen's Beef Association was formed and it responded by putting out a request for research proposals and various industry associations and companies came together to fund the research proposal from the University of Wisconsin to validate various combinations of fermentation processes.

At the same time, FSIS, and remember this was prior to the implementation of FSIS's process regulations, could have some options for addressing E. coli O157:H7 in dried and semi-dried fermented sausages. These options included cooking to lethality, achieving a 5.0-log reduction in E. coli O157:H7 or testing and probing every lot, which the report acknowledged was inconsistent with the theory of HACCP.

The Blue Ribbon Task Force document has been a great resource but to achieve a 5.0-log reduction in E. coli O157:H7, as well as other pathogens, the document recommends a kind of cook step or holding step at 90 or 110 degrees Fahrenheit for several days which may impact quality and, therefore, has limited its use.

So we just have not seen widespread adoption of the validated treatments in the document, although for those establishments that use the Blue Ribbon Task Force validated lethality treatments, it is a great resource. Next slide, please.

Because of the challenges of achieving a 5.0-log reduction the Task Force recommended another option to use a process validated to achieve at least a 2.0-log reduction in E. coli O157:H7 and test each and every lot of raw batter versus that alternative lethality option.

FSIS did not object to this option and so in the findings report, processing validated to achieve either at least a 2.0-log reduction in E. coli O157:H7 were included along with those validated to achieve at least a 5.0-log reduction.

This option does provide less assurance of product safety but it's important that raw material testing provides a high degree of confidence that there's no Salmonella present.

The raw batter testing option does provide more flexibility but it becomes very expensive to test each and every lot of raw batter. This option can be translated to products other than beef, such

as poultry or pork, where the raw batter is tested for Salmonella and a 2.0-log reduction in Salmonella is validated.

It can also be translated for stripped -- or other whole muscle products where each lot is a whole muscle and other raw ingredients are tested. Next slide, please.

As I mentioned earlier, FSIS also recommends ensuring S. aureus outgrowth is limited to 2.0-log or less during processing to ensure no enterotoxin production. In the early 1970s, there were several outbreaks in the U.S. due to S. aureus growth and enterotoxin production in fermented meats. In response, industry adopted several measures including the widespread use of commercial starter cultures.

Prior to the 1970s, many establishments used natural inoculations of meats such as back slopping where they would add meat reserved from a previous successful fermentation to the batter. This can cause a lot of failures where either the wrong type of bacteria, including pathogens, predominate and grow or harmful bacteria are added from the back slops.

Today, most fermented meat processors

either add lactic acid starter cultures or harmless staphylococci to the raw meat mix. These starter cultures are known microorganisms with proven metabolic activity added at a known concentration.

Another effective change was the addition of fermentable sugars, such as dextrose, which are like a food for the bacteria and their addition ensures reliable and rapid lactic acid production that drops the pH.

Ensuring the pH drops rapidly is important to control the outgrowth of S. aureus and can also help inhibit the growth of other pathogens and to ensure the pH drops fast enough, the degree-hours concept was also developed and is described in the American Meat Institute or AMI, Food Manufacturing Practices for Fermented, Dry and Semi-Dry Sausage Products.

The degree-hours are the amount of time in hours above 50 degrees Fahrenheit that's the critical temperature at which staphylococcal growth effectively begins, that an establishment's fermentation process can take at a specific temperature to reduce the pH to 5.3 or below in order to control S. aureus growth.

This concept has been widely adopted and

implemented effectively that, in fact, there've been no reported cases of staphylococcal foodborne illness from fermented meats in the U.S. for over 30 years.

I share this because this is really a success story in terms of widespread adoption of scientific support related to the fermentation process that was developed by industry.

Unfortunately, following the degree-hours process has not been validated to achieve any particular reductions to Salmonella, Lm or STEC. It's only been validated to limit S. aureus outgrowth -- with research staff. Next slide, please.

So how does an establishment support that the design of its HACCP system results in adequate pathogen reduction or prevention? This is where validation comes in. An initial validation is the process of demonstrating that the HACCP system, as designed, can adequately control potential outbreaks.

Under 9 CFR 417.4(a)(1), establishments are required to assemble two types of supporting documentation to demonstrate the HACCP system has been validated.

The first is the scientific or technical support for the design of the system and the second is the initial in-plant validation data that supports the HACCP system can be executed as designed. And initial validation activities encompass those activities designed to determine whether the HACCP system is functioning as intended. Next slide, please.

Now, I'm going to focus on element one of validation, the scientific or technical support, because this is where we see the greatest challenges during our verification activity. And to meet the first element of initial validation, establishments should gather scientific or technical support, which I'll talk about further. That's the published processing guidelines, journal articles, challenge studies, et cetera, for its HACCP systems that closely match the actual process and that shows the establishment's process will prevent, reduce or eliminate the hazards identified in the hazard analysis and it should identify the critical operational parameters from the scientific support relevant to the establishment's process. Next slide, please.

So examples of scientific or technical

support include the following. First is published processing guidelines including FSIS guidelines. FSIS does not have any guidelines currently that are food critical operational parameters for ready-to-eat shelf-stable meat and poultry products. We have a guideline related to Lebanon bologna but it does not include any of what we think of as safe harbors.

Some establishments will apply -- cooking parameters but, again, like the Blue Ribbon Task Force issue, cooking does not always result in the desirable quality establishment's want.

Another example are best practice guidelines. An example would be the Blue Ribbon Task Force document I've been talking about or the AMI Good Manufacturing Practices for Fermented, Dry and Semi-Dry Sausage Products that I also mentioned earlier that includes the degree-hours concept for controlling S. aureus.

Another example are peer-reviewed scientific data/information and this is what we commonly see and in the form of journal articles. Challenge or inoculated pack studies may also be used so this is also a common option but it can be costly.

Another option is pathogen modeling

programs and, unfortunately, there's only one model currently available that has been validated from Denmark and it's only been validated to support up to a 3.0-log reduction in Salmonella and STEC.

There is also a validated model from the University of Wisconsin that can support shelf stability but it's limited to the supporting shelf's ability.

And then last, are regulatory performance standards. An example would be something like the patty regulation for prescribed cooking parameters. However, there aren't any for multi-hurdle lethality products.

But during our verification activities we do find establishments that have no scientific support for their lethality treatment.

They may have the AMI's Good Manufacturing Practices for Fermented, Dry and Semi-Dry Sausage Products for fermented products on file to support the degree-hours but as I talked about, that's only validated to potential S. aureus outgrowth. Otherwise, we may find that there is not scientific support on file that demonstrates any particular reduction in Salmonella and Lm is achieved. Our next slide, please.

Considering these types of support there are just a lot of challenges for identifying and applying even the readily available scientific support which would be in the form of journal articles or the Blue Ribbon Task Force document I talked about.

So there is available literature that supports a 5.0-log reduction can be achieved for fermented and dried meat and poultry products, but these would make these either high fermentation temperature and achieving a low pH, which are some of the options from the Blue Ribbon Task Force, applying a low temperature heat step following fermentation, using a long drying time or applying Appendix A time, temperature, humidity parameters after fermentation and before drying. But again, establishments don't always want to use these processes because they can impact the quality of the product.

Most establishments want to rely on fermentation and drying alone and have varying treatments that are used including low fermentation temperatures. So it's difficult for establishments to be able to find readily available support that fermentation and drying alone achieve a 5.0-log

reduction. I'm aware of one main study used from one starter culture company. Next slide, please.

It gets even more challenging when we consider all of the parameters that impact the effectiveness of fermentation, culturing and drying. As I indicated earlier, to meet the first element of validation, once the establishment identifies scientific support, it then needs to identify all of the critical operational parameters and ensure they're consistent with those used in the actual process.

So even when an establishment can find a process validated to achieve a 5.0-log reduction, it then needs to make sure it can implement all the critical operational parameters to justify any differences which can be challenging. And as we saw with the Lebanon bologna outbreak in 2011, differences in critical operational parameters can lead to illnesses.

I'm not going to read through all the critical operational parameters on the slide, but I'm sharing this to show how complicated these processes are and how so many variables can impact the effectiveness. Next slide, please.

So to summarize, there's an increasing

interest in producing artisanal/niche shelf-stable ready-to-eat fermented, salt-cured or dried products that rely on multiple hurdles for lethality. There have been a few outbreaks associated with these types of products. I've talked about a few and there have been approximately eight outbreaks in the U.S. over the last 50 years from FSIS-regulated products.

Little scientific support is available for establishments to support lethality and when it is available it can be difficult to match the critical operational parameters to those used in the actual process.

FSIS is in the process of developing a guideline but there's little scientific support we can share. So the lack of scientific support may raise enforcement questions that FSIS is going to need to address. So this is really where enacting -- would be of great value and why we brought this charge? Next slide, please.

So we have two NACMPI Committee questions and we're seeking input on the lack of scientific support and control of hazards for producing multi-hurdle lethality products that, again, may raise enforcement questions.

So first, what action should FSIS take when it determines an establishment lacks scientific support for the lethality treatment of a fermented or cured or dried product? And we've given some examples here for the Committee to consider when answering this question.

So for example, should FSIS take enforcement action and require scientific support for 9 CFR 417.5(a)(1) and 9 CFR 417.4(a)(1) which will most likely result in the need for a challenge study by the establishment or should we allow establishments to test and hold indefinitely?

This option is not currently considered acceptable because it's inconsistent with HACCP to not rely on controls for preventable measures. Also, testing can't detect all possible pathogens. This can be costly to test for several pathogens at once. In addition, pathogens are often not evenly distributed so it's hard to test enough pieces to give confidence -- to treat a pathogen.

Another option to consider is if we could allow establishments to combine multiple scientific support documents, such as journal articles, even if none of them alone support the critical operational parameters used or allow scientific support that

demonstrates less than a 5.0-log reduction. This can be difficult for FSIS personnel to verify but this option may be used in combination with increased FSIS testing.

Another option to consider is for FSIS to use regulatory discretion and allow establishments to produce without scientific support or the Committee may consider a combination of the above or other options. Next slide, please.

And our second question is how can FSIS assist industry in gathering scientific support in these cases and facilitate filling research gaps even though it's not a research-funding organization?

On Tuesday, during the Salmonella public meeting, Isobel Walsh from FSIS's Office of Public Health Science shared a research priority and study from FSIS related to the need for research to estimate drying time for different diameter dry and semi-dry fermented sausages to ensure a 5.0-log reduction in Salmonella.

And FSIS has had several research priorities posted on its website related to fermented, raw-cured and dried products. However, we just have not seen research completed to fill

these gaps.

So is there some way FSIS or even other organizations could facilitate the sharing of proprietary data so that more safe harbors are available that better match the types of products establishments want to produce?

And so with that I can take any questions. Next slide, please.

MS. GREEN: Are there any Committee members that have a question?

MR. GREMILLION: (Indiscernible?)

MS. GREEN: Yes.

MR. GREMILLION: Hi --

MS. GREEN: -- Please state your name and affiliation for the record.

MR. GREMILLION: Hi. This is Tom Gremillion, Consumer Federation of America. I had two questions.

One, at the outset of the presentation you said there's rising interest in these sausages and I wondered if you just had the data or other information that might illustrate the magnitude of the increased interest and my second question is what is the status quo now when FSIS determines that at the facility, the establishment doesn't need to

have -- it sounded like it's number one of the options presented but I wanted to clarify that. Thanks.

MS. SILVERMAN: Yeah. So unfortunately I don't have data on the volume of the category. Some of that comes just anecdotally from ask FSIS questions we've received and then, yes, in terms of FSIS actions, currently it would be to follow the regulatory requirements and document non-compliance and then corrective actions to come into compliance would necessitate gathering scientific support.

MS. GREEN: Are there any other questions before I move to the questions in the chat feature?

MS. CURTIS: This is Pat Curtis from NC State University and I put my question in chat, as well. But does FSIS not contribute research priority needs to NIFA when they're collecting their research priorities for what they're going fund for the coming year?

MS. SILVERMAN: Yes. I know we do share our research priorities with NIFA and have shared these in the past but I'm not aware of, you know, how the decisions are made from their end to fund research. But we do share our research priorities with the Agriculture Research Service as well as

NIFA.

MS. GREEN: All right, this is Val Green, again. I'll start with a question in the chat feature from Greg Gunthorp, Gunthorp Farms.

Can you share these eight outbreaks of USDA dried, salt or fermented products? He would like to research whether these establishments are following good manufacturing practices.

MS. SILVERMAN: Yes. I can see what details we're able to provide. I can say three of the outbreaks were related to the S. aureus enterotoxin issues I mentioned in the 1970s before the degree-hours concept was developed and before NIFA starter cultures were implemented.

But then most recently we do have information, in 2011, about the Lebanon bologna outbreak that was associated with E. coli O157:H7 and that information is in a guidance document available online and they are the issues we found where the establishment had scientific support but it really didn't match the actual process that they were using.

And there was another outbreak in 2010 associated with products where slicers were contaminated with Salmonella and they were added

after the lethality treatment.

And then were some other outbreaks in the '80s and '90s, again, that led to that Blue Ribbon Task Force document where E. coli O157:H7 was identified in salami and that was associated with other processing for insufficient lethality from the fermentation and drying process.

MS. GREEN: Thank you. This next question is from Dr. Lynn Knipe, Ohio State.

You mentioned one study from a culture company that had validated high temperature fermentation to achieve low pH. Can you tell us which company had done this?

MS. SILVERMAN: Yeah, so the high temperature fermentation and the low pH, that actually comes from the Blue Ribbon Task Force, some of the options involved those combinations, but the starter culture company that has a study that's available is from Chr. Hansen.

MS. GREEN: This is the last question that I have in the chat feature and then we'll move on to verbal questions if there are any additional ones. This is from Greg Gunthorp, Gunthorp Farms.

Does USDA have an expected deadline on a compliance guideline document on dried, cured,

salted or fermented yeast? His estimation is that it was promised 19 years ago.

MS. SILVERMAN: Yes. So I do know that there was an interest in this issue since the beginning of HACCP and it has been a challenge of validation.

We are working on the guideline, as we mentioned, and are really interested in the feedback from NACMPI before we would put that out.

MS. GREEN: Thank you. As a reminder to the Committee members and the audience, you may press #2 to ask a question and please state your name and affiliation for the official record before you ask a question. Are there any additional questions?

AT&T EVENT PRODUCER: We have one question here.

MS. GREEN: Okay.

AT&T EVENT PRODUCER: Dr. Byron go ahead. Your line is unmuted. Dr. Byron, go ahead. Your line has been unmuted.

DR. WILLIAMS: Thank you. Byron Williams, Mississippi State University Extension. My question is have there been any documented cases of foodborne outbreaks with these type products since 2010 and 11

with the Lebanon bologna?

MS. SILVERMAN: No. That's the last -- the 2011 is the last documented outbreak associated with one of these types of fermented, salted or dried products produced under FSIS inspection. But there have been some outbreaks in Europe during that time but there haven't been any in the United States.

DR. WILLIAMS: Okay. Thank you.

MS. GREEN: Victor, do we have any more questions?

AT&T EVENT PRODUCER: I don't see any other questions at this time.

MS. GREEN: Okay. I have a question in the chat from Dr. Eberly in Maine.

Is the draft guidance available for Committee review?

MS. SILVERMAN: No, not at this time.

MS. GREEN: I don't see any additional chat questions so we'll go ahead and move to the next presentation. Thank you, Meryl. Next slide, please.

Next is Robert Witte who will discuss the intended use of intact box beef primal and sub-primal products. I'll go ahead and turn it over to Mr. Witte.

AT&T EVENT PRODUCER: Mr. Witte, can I assure your phone is not on mute? Mr. Witte, if you are on the line please press #2 so I can identify your line. Please go ahead.

MR. WITTE: There we go. Can you hear me now?

MS. GREEN: Yes.

MR. WITTE: Okay. Perfect. Thanks, Val. Next slide.

I will first begin by reviewing the charge we have placed in front of you today, then cover the history, background and data in more detail to give the charge context and then close the presentation by reviewing the charge again. After the presentation is complete we will open the floor for questions. Next slide.

As a basic introduction, STEC is an acronym for Shiga toxin-producing E. coli. Some strains of STEC may cause severe illness due to the presence of Shiga toxin and other virulent factors. STEC can reside in the intestinal track, mouth, hide and hooves of live cattle and can be transferred to the carcass during the slaughter dressing process.

It is important to understand that STEC is not inside the raw intact muscle itself. STEC

contamination occurs when it is transferred to the meat surface during the slaughter dressing process.

Now that we have a general idea of what STEC is and an understanding of where STEC comes from, let's look at why the location of STEC contamination in various raw beef products is important.

As a note, any references to E. coli O157:H7 and STEC were changed to STEC in these slides for simplicity and consistency. E. coli O157:H7 and the six non-O157 groups which include O26, O45, O103, O111, O121 and O145 are adulterants in raw, non-intact beef and intact beef products intended for raw, non-intact use.

Although there are many other Shiga toxin-producing E. coli, this presentation refers to those 7-0 groups which are collectively referred to as STEC in this presentation. Next slide.

Unlike other species and pathogens, there is a unique relationship between STEC and certain raw beef products. STEC has a low infectious dose and has been linked to -- with serious, life-threatening human illnesses.

Also, raw beef products are frequently consumed in a rare or medium rare state which

presents a public health risk as cooking to a rare or medium internal state does not destroy STEC but may be below the product's surface. For these reasons, STEC adulterates certain raw beef products as I will discuss. Next slide.

In determining which products are eligible for FSIS sampling for STEC, FSIS distinguishes intact cuts of muscle that are distributed for consumption as intact cuts separately from non-intact products. FSIS also distinguishes intact cuts of muscle that are further processed into non-intact products prior to distribution for consumption from intact cuts that stay intact.

Comminuted or non-intact cuts are eligible for FSIS sampling. Intact cuts intended to be used in non-intact products are eligible for FSIS sampling. The photos here show two different types of beef products consumers prepare and eat and illustrate the distinction.

On the left are intact steaks. I say intact to mean the meat interior remains protected from pathogens migrating below the exterior surface. The surface is intact and any STEC that's present would be restricted to the exterior only, not inside the steak itself.

In this example it's easy to see how heating to even a rare or medium internal state will kill any STEC that is restricted to the outside surface of the steak.

On the right you'll see a rare hamburger. FSIS recommends heating ground beef to an internal temperature of 160 degrees Fahrenheit. This photo is used to illustrate the risk posed by eating a rare or medium hamburger. Now, if STEC is present it is no longer restricted to only the outside surface like it would be in the intact steak. It now may be pushed or spread anywhere throughout the ground beef, including to the middle where it would not be killed by the heat applied to the exterior when cooking to a rare or medium internal state.

For this reason, FSIS samples and tests intact cuts of beef that are to be further processed into non-intact products prior to distribution for consumption in the same manner as non-intact products, since STEC may be introduced below the surface of these products. Next slide.

Currently, FSIS does not sample or test boxed beef primal and sub-primal products for STEC if they are intended for intact cuts. At the heart of the charge today is the concern that these boxed

beef primals intended solely for intact use and which are not subject to FSIS's STEC testing are being used to make raw ground beef resulting in STEC-positive ground beef in commerce, illnesses and death.

Here are some visuals of boxed beef showing the packaged primals in the box and relative sizes and weights of a primal compared to a consumer-ready packaged steak and ground beef. There is some evidence that retailers buy the boxed beef and use the primals either in whole or trimmings left over after making steaks to create raw ground beef.

The charge before you today is if an establishment identifies boxed beef primal or sub-primal products as intended for intact cuts, should FSIS continue not to sample or test these products?

If yes, how can the current system be strengthened? If no, what criteria should FSIS use to determine which products should be eligible -- should be subject to sampling and testing for STEC?

For the purposes of this discussion you'll hear terms like vacuum packaged and boxed beef. Vacuum packaging equipment removes the air and seals the product inside the bag. The sealed primals are then packed -- placed into cardboard boxes and

shipped as boxed beef, as shown in the photos here. Those are simply packaging methods, boxed beef in a box. Beef in a box is not required to be vacuum packaged and may not be vacuum packaged in every case.

As you will see in future slides, industry associates vacuum packed -- vacuum bagged primals with products intended solely for intact use, hence why I use the term.

With that in mind, let's dive deeper into the sampling history. Next slide.

In 1994, Mike Taylor, who was the administrator of FSIS at the time, announced that E. coli O157:H7 adulterates raw ground beef and quotes from that speech are on this slide. FSIS began testing for E. coli O157:H7 in ground beef in 1994. Next slide.

In 1999, FSIS announced in the Federal Register that in addition to ground beef, raw intact cuts of beef to be processed into non-intact cuts found to be contaminated with E. coli O157:H7 would also be considered adulterated.

If the latter two types of the products are found to be contaminated with E. coli O157:H7 they must be made ready to eat, that is to receive a full

lethality treatment to produce a product that can be safely consumed without any further cooking or preparation or the product will be deemed adulterated.

In 2000, FSIS made it clear that establishments needed to identify the intended use for consumers of the finished product under HACCP. In 2002, in response to data suggesting E. coli O157:H7 was more prevalent than originally thought, FSIS has issued a Federal Register Notice for establishments producing non-intact beef, as well as intact beef, to reassess their HACCP plans for E. coli O157:H7 in light of this new information. Next slide.

In 2004, FSIS issued a directive that said FSIS may sample trimmed and other raw ground beef components in response to ground beef positives as they were the source materials used to make the positive ground beef.

In 2007, FSIS began testing trim and other raw ground beef components on a routine basis.

In 2011, FSIS announced that certain non-O157 STECs are adulterants in raw ground beef, other non-intact beef products and raw intact products intended for use in non-intact products.

In 2012, FSIS began analyzing beef manufactured trimmings for those non-O157 STECs. Next slide.

In the current version of FSIS's Sampling Directive, that is Directive 10010.1, Revision 4 issued in 2015, the list of eligible products is shown here and includes beef of any size that the establishment intends for use in raw, non-intact products or when the intended use is unclear. The directive identifies the bolded items here as products eligible for sampling.

Note that the focus is not exclusively on trimmings. Though there are some specific product groups listed, like trimmings and two-piece chucks, it's important to remember that parts of any size and in any packaging can be eligible for sampling if intended for non-intact use or the intended use is unclear.

The intended use is very important. As stated in the directive, the product's intended use is a key factor in determining whether FSIS collects samples. FSIS samples products intended for use in raw non-intact products such as ground beef, mechanically tenderized, needled, vacuum-marinated or when the intended use is unclear.

Inspection program personnel are not to sample products that the establishment intends for use in intact or ready-to-eat products or product that will receive full lethality treatment at another federally inspected establishment.

If the product is to receive a full lethality treatment at another federally inspected establishment, IPP are to verify the establishment's hazard analysis and flow chart show that the product is intended for one of these controlled uses and that the establishment has controls that ensure the product is used as intended. If not, IPP are to collect the sample. Next slide.

This where we move to the intended use portion of the HACCP regulations. The HACCP regulations require establishments to identify how the product will be used and consumed to inform their hazard analysis decision making. FSIS primarily relies on the establishment to identify each product's intended use and then FSIS determines which products are eligible for FSIS sampling and testing. Here is that regulation.

When an establishment identifies boxed beef primals to be intended for intact use, that intended use is most commonly communicated through posting a

statement on the company webpage and/or adding a statement on a bill of lading or invoice when sold to distributors or other customers.

As an example, a webpage statement may read, [Establishment Name] produces primal products packaged in vacuum bags intended solely for intact use. [Establishment Name] expects any customer who purchases vacuum packaged primals for other than intact product address that specific usage in their HACCP plan.

FSIS currently views this as adequate support for their intended use determination. Currently, when products -- when product is intended for intact use and there is a webpage statement and/or invoice statement, FSIS does not sample and test for STEC. Evaluating this is associated with your charge today. Next slide.

Whether it be an issue with the sending of the message or the receiving of the message, the intended use is not being carried out at the retail level. These products continue to be used to make ground beef. If the Committee recommends that FSIS continue to rely on the establishment's intended use and not sample intact beef products for STEC, investigating ways to strengthen this communication is

one part of the charge in front of you today.

During meetings with groups such as at the Conference for Food Production in a response to recalls and illness investigations, FSIS find retailers to be unaware of the intended use of boxed beef primals or the risk -- or the risks of grinding boxed beef primals.

First, the intended use statement does not describe the risks associated with grinding the boxed beef. Second, the intended use statements instruct customers that grind the boxed beef to address that usage in their HACCP plan.

It's important to note that retailers do not have Hazard Analysis and Critical Control Points, or HACCP plans, and may not know what HACCP means when reading that statement. Third, retailers are found to be unaware if boxed beef has an intended use or the need to contact the producing establishment to ask about the intended use. The concept is foreign to them.

And finally, retailers don't always buy directly from the establishment. They may buy from multiple brokers and distributors based on best prices, delivery dates and demand. These vendors may or may not have -- the intended use statements on

their invoices to each retail customer or clarify what the intended use means.

To quantify this, in 2019 FSIS began collecting specific intended use data associated with each of the roughly 500 retail ground beef samples FSIS collects across the nation at retail firms. The data is entered by FSIS personnel on each sample form questionnaire for each retail ground beef sample collected.

The data shows 82 percent used vacuum packed -- vacuumed primals in whole or trimmings thereof to make the ground beef, 83 percent of the retailers were not aware of the source material's intended use, 93 percent of the retailers did not apply any STEC controls to eliminate STEC on the boxed beef primals prior to grinding the beef. Next slide.

Webpage and/or invoice statements identify vacuum packaged boxed beef to be intended -- to be solely for intact use and FSIS does not sample and test these products for STEC. Evidence shows retailers use vacuum packaged boxed beef to make ground beef and do not apply additional STEC controls to eliminate STEC on the boxed beef primals prior to grinding. The data shows the producer's intended use is not being carried out.

FSIS takes regulatory action, including trace-back activities, initiates recalls, retains or detains affected products, verifies disposition of affected products, conducts public health risk evaluation and food safety assessments and conducts follow-up testing at producers and suppliers in response to illnesses or STEC-positive retail ground beef samples.

Currently, FSIS does not take action against the producing establishment or retailer strictly because the intended use is not followed. Too -- this, too, is part of the charge in front of you today, to advise FSIS how to report. Currently, there are over 98,000 retail firms and FSIS collects approximately 500 retail ground beef samples each year from retail firms. Next slide.

As we close, here's a diagram for those of us that like visuals. To be clear, I am not saying every primal intended for intact use is contaminated with STEC nor am I saying illness results every time a primal intended for intact use is ground at retail. I am not saying either of those. I provide this diagram to illustrate that not all beef products and retailer handles are the same in terms of the STEC controls applied by the producer.

Think about if you were that butcher there working in a retail market. Put yourself in their shoes. Would you realize the difference or risks between the two sources?

On the bottom, the trimmings in a combo are intact pieces of beef intended for non-intact use. Those products are eligible for FSIS sampling for STEC whereas on the top, the primal is intact beef intended solely for intact use and is not eligible for FSIS sampling for STEC.

If you were that butcher, would you know the primal is intended solely for intact use? Would you know what that intended use means, recognize the risks or understand the need to apply a STEC control measure before grinding it or do you just grind the beef you have on hand to keep the retail case full, unaware of any intended use or risks?

As discussed previously, evidence shows retailers remain unaware of any intended use of these products. The illustration here shows the gap between the supplier's intended use that may be posted on a webpage which currently helps inform whether a product is eligible for FSIS sampling and how the products are used in commerce.

Whether that be grinding the whole primal or

trimmings generated after making steaks, retailers make ground beef from primals and producers -- from primals the producer intends to be fully for intact use which has, in certain cases, resulted in recalls and outbreaks. Next slide.

FSIS's issuance of the grinding records rule which require establishments and retailers to keep records of the source materials used to create each lot of ground beef has certainly enhanced FSIS's trace-back abilities in response to positives and illnesses.

In 2014, FSIS identified three separate ground beef positives through retail ground beef sampling generating three separate recalls. In each of these three positives, the trace-back revealed the retailer made ground beef from source materials intended for intact use. There were two ground beef positives identified through FSIS in-plant testing. Trace-back showed both establishments were separately grinding the same lot of product intended for intact use from the same producing establishment resulting in one recall.

There have been three separate illness outbreak investigations and a death associated with retailers grinding primals intended for intact use

also resulting in three recalls. The details for the most recent outbreak and recall were posted on the FSIS webpage in July 2020 in an after-action review report.

In each of the seven recalls on this page the source materials used to make the ground beef were intended for intact use and not sampled by FSIS at the producer. However, these products did not remain intact as the producer intended.

Now, let's summarize the charge placed before you today. Next slide.

When considering consumer-ready intact steaks and roasts, FSIS is confident that many of these products will remain intact when sold at retail, for example, individually packaged -- individually vacuum packaged steaks. However, larger primals that are intended solely for intact use, that is vacuum packaged primals, are being used to make ground beef for sale to consumers.

FSIS is seeking input on how FSIS can reduce STEC positives, outbreaks, recalls, and deaths that occur when downstream processors are commonly unaware of the product's intended use or the risks of grinding such products. FSIS is requesting the Committee's comments and recommendations in response to the

following questions.

If an establishment identifies boxed beef primal/sub-primal products as intended for intact cuts, should FSIS continue not to sample or test these products? The follow-up questions are on the next slide. Next slide.

If yes, how can the current system be strengthened? Please consider what are all of the options producing establishments should have to communicate their intended use to customers?

What steps should producing establishments take to verify the intended use was both understood and followed by the further processor or grinder?

What -- how should this be documented or tracked so that the establishment and FSIS know that the product was used as intended?

What steps should further processors or grinders take to seek out that intended use information from the producing establishment?

In addition to verifying HACCP plan reassessment, what actions should FSIS take at the producing establishment when products intended for intact use are used to make raw non-intact beef?

If no, what criteria should FSIS use to determine what products -- which products should be

subject to sampling and testing for STEC? Please consider what are the size or dimension thresholds, cuts or product characteristics such as grade, individual versus bulk packaged, et cetera, FSIS should use to be confident the product intended for intact use will remain intact through consumer cooking?

And then for both, what changes to FSIS sampling and testing, HACCP verification instructions or regulations does the Committee believe would help effect the Committee's recommendations? And what outreach methods and messages would be most effective to federal establishments and retail firms?

And with that we can open it up for questions.

MS. GREEN: Thank you, Robert. Do we have any questions from the Committee members? You may unmute yourself and ask a question.

MS. WILLIAMS: This is Sherri Williams with JBS and two things, actually. First was a point of clarification for one of your statements on slide 15. It almost sounded like you were saying that the slaughterhouse or the manufacturers of the primals treat the intact use products intended and the non-intact use products differently with different

interventions or different processes at the manufacturer and so I just wanted to clarify and see if that's what you were saying or if there was something else that you had meant by that comment.

And secondly, on 16 -- slide -- page 16, if you could go into a little bit more detail when you talked about the recalls where it's revealing that retailers make ground beef from the source materials intended for intact use. Was that the actual whole item, like the whole sub-primal or was it trimmings derived from intact sub-primals? Thank you.

MR. WITTE: Thanks for that. Yeah. Sorry, in slide 15 I just mostly wanted to indicate the products that FSIS does or, you know, that are or are not eligible for sampling so I apologize if that -- if I didn't communicate that well.

In terms of 16 for the outbreaks and retailers there, we don't -- I'm not aware of whether they just -- they ground the whole primal or just the trimmings from the primal. Some of those are, you know, each has an individual situation and some have multiple retailers or different things happen at different retails but I don't have the evidence on each one of whether they ground the whole thing or just parts of the primal or, you know, a bigger piece

or whatever, the steak or --

MS. SORSCHER: Hi. This is Sarah Sorscher from Center for Science in the Public Interest. I had a question I submitted in writing but I'm curious if you assess what percent of retail samples, you know, for which the retailer doesn't know the intended use but I'm just curious if you've assessed, you know, looking overall at boxed beef produced in this country, what percentage is currently eligible for testing as intended for non-intact use and then, you know, if you were to test it all, what
-- how greatly would that expand your -- the sampling that you needed to do?

MR. WITTE: This one might be a good one, I guess, we could correlate with industry on it in terms of the percentage, I mean whether we do volume, you know, exiting a slaughter facility, how much turns into trim, how much turns into primals, how much turns into certain products that are or aren't eligible. I don't have that in front of me here today. I don't know if anybody else can speak to that in terms of volume or ratios.

MS. EDELSTEIN: This is Rachel. I don't think that we have assessed that. We recently put out, you know, some updates, some of our testing

updates for our -- when we were -- in our cost updates for when we were assessing the effects of sampling all of the beef products for non-O157 STEC so we can go and check in there and see if we have any estimate in there and get back to you.

Also, well, since I'm on. Did we address the first question about -- from Sherri about, you know, if they're applying different interventions at the establishment depending on whether the product's intended for intact or non-intact?

MS. GREEN: Hello, Rachel. This is Val Green again. Is that question in the chat feature?

MS. EDELSTEIN: Well, she asked it verbally.

MS. GREEN: Oh, I'm sorry. Okay.

MS. WILLIAMS: Hi, Rachel. This is Sherri Williams. I believe it was just a point of clarification and I believe Mr. Witte clarified that it was an example of just the processes and not insinuating that different processes were -- so I feel sufficient with that. Thank you.

MS. EDELSTEIN: Okay. Thanks.

MS. GREEN: All right, Victor. I believe I believe there are some hands raised to ask a question.

AT&T EVENT PRODUCER: If they were on the speaker line, oh, here we go. Dr. Byron, your line is

unmuted. You can go ahead.

DR. WILLIAMS: Thank you. Byron Williams, Mississippi State. Just curious Mr. Witte, what percentage of the intact carcasses are being sampled at the slaughter facilities prior to then undergoing breakdown?

MR. WITTE: So we try to avoid any carcass sampling at all costs. We sometimes have procedures, a trace-back or some of that but we try to get it as far downstream as we can within the establishment.

So once that carcass is broken down and we know what, you know, each product, each direction each product's going its own way, we can differentiate those from, you know, being intended for intact use from those being, you know, whether it's made non-intact on site or those, you know, sent out that are intended for non-intact use.

So in terms of actual carcass sampling that's essentially zero. Does that answer your question?

DR. WILLIAMS: Yes, sir.

MS. GREEN: Are there any other questions before I move to the chat -- the questions from the chat?

AT&T EVENT PRODUCER: I don't see any other

questions at this time.

MS. GREEN: Okay. This next question is for Rachel Edelstein. This is from Ray Gunthorp from Gunthorp Farms.

Have we ever considered that the Meat and Poultry Act gives some of the largest corporations and the food supply extensions from USDA meat and poultry inspections and prestige retailers yet the same implementation of the Meat and Poultry Act and FDA Model Food Code makes it very difficult for very small farmers to access inspection options? Are we addressing this in the Committee, how the current MPA and FDA Model Food Codes are not necessarily equitable to small farmers' access to the marketplace?

MS. EDELSTEIN: Hi. To actually require that the retailers be under the same requirements as the federal inspected establishments would take a legislative change. So that's outside the scope of the Committee but if the Committee has -- I mean we're definitely interested in if there's suggestions from the Committee on how to better -- I mean, some of the things that Bob Witte raised, if there's better ways to communicate and ensure that the intended use is understood throughout the process, that's the sort of thing that the Committee, you know, that we're

interested in input on. Or, you know, if there's different -- there's different, you know, any recommended changes for, you know, in our verification activities, too.

MS. GREEN: Thank you. The next question is from Casey Gallimore, Meat Institute. Has there been an attempt to educate retailers on intended use in the past? If so, what was the program so we might identify potential ways to improve communication? If not, are there plans to do so in the future?

MR. WITTE: I can maybe touch on some of this. We have proposed the topic a couple times for the Conference of Food Protection so, you know, they can reach their customers and make the concept more visible, I guess you could say. I believe industry has presented to different, I guess, retail organizations or, you know, the concept of intended use.

We also have discussed how to best communicate that message publicly. We don't have a, I guess, pamphlet or a brochure or anything right now but that may be part of the recommendations here of how do we, you know -- like I said earlier, I don't know if it's part of the sending or the receiving of the message and then also provided that note that

there's, you know, just under 100,000 retailers out there, you know, how best do we reach all of them? How do we get that message out? So there has been some in the past but I think, you know, this group can really give us some information on how to move forward with that if that's part of the recommendation.

MS. BARLOW: This is Kristina Barlow. I'll just add to what Robert stated. We did submit an issue to the Conference for Food Protection biannual meeting that's available publicly on the CFP website. We can provide that. And that recommends updating the current guidance that the CFP provides for grinding recordkeeping to include -- and the feedback that we've received from the conference, as Robert mentioned previously, is that they don't understand that there's different regulatory requirements for the safety of ground beef. They think that all beef is treated the same as far as the feedback we've received from that conference --

MS. GREEN: Thank you, Kristi. Victor, are there any other questions?

AT&T EVENT PRODUCER: I don't see any --

DR. HARRIS: This is Joe Harris from the Southwest Meat Association. Just a question for Mr. Witte. I'm just trying to get a better feel for the

scope of what we're talk -- the problem. I believe you told us on one of your slides that there are about 500 retail samples per year being collected so since 2014 there's been three positives identified through that program and also since 2014 there's -- you said two ground beef positives through FSIS in-plant testing.

Relatively speaking, how many samples per year are done to the FSIS in-plant testing? Two positives over a six-year period doesn't sound like that many.

MR. WITTE: Yeah. So this presentation is about the intended use part, so just things that fall under that umbrella. So we collect roughly 500 ground beef samples at retail every year. So, you know, obviously plus or minus, but that's the target, around 500 a year. And then in terms of federal establishments we collect about 10,000, again, plus or minus. And then trimmings, you know, they're all kind of different. They all have their own numbers there.

So the three positives from ground beef are the ones that have an intended use impact as part of this discussion and are coming out of that 500 a year. The two positive ground beefs are not the only ground beef positives we've had. It's just those are the

ones that fit under this presentation, this topic and then the three, you know, the three outbreaks are, you know, not positive sample related. Does that answer your question? That makes sense?

DR. HARRIS: Yes, so I was just trying to get a little bit of a feel for the denominator that we're dealing with.

MR. WITTE: Yeah, I mean, it's hard to say in terms of, you know, when we collect a sample we don't say the intended use in those. I think we can go back to some of the, you know, the 500 that we collect from retail and we can work through that intended use information that we got on those questionnaires so if we go back to slide 13 where it talks about vacuum-packaged primals, it talks about, you know, did they or didn't they apply additional controls.

And so, you know, I don't want to make the blanket statement that every vacuum packaged primal in every case is intended for intact use. It's just, you know, without having our investigators go through a lot of paperwork to track back every, you know, individual source for a sample, whether it comes back positive or not, we collect this kind of high level information and so that only started in 2019 so about

a year, year-and-a-half old.

But in terms of, you know, data prior to that we didn't collect the intended use information for every ground beef sample so I just -- I can't speak to which ones were -- came from product intended for non-intact use versus those that came from products intended for intact use.

DR. HARRIS: Thank you.

MS. GREEN: Thank you. And just for the audience, as a reminder please press #2 if you have a question. State your name and affiliation for the official record before you ask a question. I have a question from Dr. Eberly, State of Maine in the chat section.

If both FSIS and large slaughterhouses are aware that many primals labeled intact are likely to be used for non-intact use, does this represent a known hazard they should address in their own HACCP system?

MR. WITTE: So I think this is part of the discussion, right. I mean, in terms of labeling I -- you know, just to point there, there can't be intended use labeling so we don't allow a label to say the statement "Intended for Intact Use." So -- but in terms of the -- your, you know, your general premise

there, yes, that's part of the discussion here of if an establishment, you know, considers that intended use as part of the decision making and then later evidence shows that it's not being followed, that's part of the charge here is how should FSIS do that? How should that be evaluated?

So yeah, it sounds like you're on the right track. I agree with you and, kind of, the answer to that will come as part of our discussions, I think, today.

MS. SORSCHER: Hi. This is Sarah Sorscher from CSPI, again. Can you clarify the statement you just made saying that you can't have a label -- can't be intended use? What is preventing you from requiring that of establishments?

MS. EDELSTEIN: We wouldn't -- I'm sorry. We wouldn't -- this is Rachel Edelstein. We wouldn't approve that kind of label.

MS. SORSCHER: Can you explain a little more the reasoning there?

MS. EDELSTEIN: We have -- because we don't -- our position has been we don't want labeling to be used as a control.

MS. GREEN: Victor, are there any other questions?

AT&T EVENT PRODUCER: No, I don't see any other questions. There's a speaker with a hand reach. Your line is currently unmuted so you can go ahead.

MS. CONKLIN: This is Tina Conklin with Michigan State University. Do you not label -- so if it has tested positive, combos that would be tested as tested positive for cooking only so you are, in fact, defining an intended use on that?

MS. EDELSTEIN: We do allow "For Cooking Only" and we have -- and we've put out guidance and instructions for how to review, I mean, you know, how to approve and how inspectors would review the use of that label. If the product is also positive it couldn't just say -- it would have to go under a seal or other kind of control to a cooking establishment.

MR. WITTE: Yeah, and what we're really trying to get as is everything is controlled through HACCP so that "For Cooking Only" label we do allow that but it's completely voluntary. That product still must meet the same standards whether it has that label or not under its HACCP system.

So if they're making a decision, it's -- you know, it's for cooking only, it's intended to be cooked at a federal establishment, they must show that it was sent to a federal establishment for cooking

through HACCP independent of whether they put the label on it or not. And then, like Rachel said, if it's positive that's part of their corrective actions to show how that product was cooked, again, whether it had that label on it or not. The control still comes through HACCP so use of that label is voluntary.

MS. CONKLIN: And then just to clarify one other point so right now you don't have the -- you don't let -- sort of use labeling as a control but you do let them put these statements on their websites that say this is intended for intact use and if you decide to grind it you have to take account for that in your HACCP plan.

What is the -- what are retailers supposed to do in their HACCP plan when they're getting beef that, you know, wasn't tested for STEC and they don't know if it contains STEC and how can you grind that and in a way that accounts for the safety risk?

MR. WITTE: And I think these are part of the discussions we're going to have today. I don't want to dodge your question or make it seem like I'm intentionally not answering it but this is the question posed of, you know, the retailers don't have HACCP plans and so -- but to the same point what do they do? How are they informed? You know, what

actions are expected of them? Do they know that?

You know, it's that two-way communication of, you know, here's sending and receiving of the message and so I think that's going to be part of our discussions today of how does that message get to them and what is expected of them in terms of, you know, do they buy that or not? Do they apply additional controls or not? You know, how do they work with their producer to get the products that they want based on what they're going to produce?

Yeah, I'm sorry I can't give you a good answer. I think that's part of our discussion today.

MS. GREEN: Are there any other questions for Robert Witte?

AT&T EVENT PRODUCER: I don't see any at this time.

MS. GREEN: Okay.

MS. EDELSTEIN: Val, I thought there was one about -- above about equivalence and I thought I saw one about bench trim, too, in the chat.

MS. GREEN: All right. I'd like to circle back to Meryl Silverman, a question on equivalence I believe it's for her. This is from Greg --

MS. EDELSTEIN: Actually, I can probably answer that, Val.

MS. GREEN: Okay. From Greg Gunthorp, Gunthorp Farms.

Is your determination on equivalency of foreign inspection systems for dried products being imported into the U.S. consistent with U.S. inspection activities?

MS. EDELSTEIN: Yes. Again, this is Rachel. If the country has been -- if we've determined that it's equivalent to ship these types of products to the United States we are -- we have verified and we verify on an ongoing basis that the country maintains inspection procedures for these products that are comparable to the ones -- at least equivalent to the ones that FSIS is using.

MS. GREEN: Thank you, Rachel. Are there any other questions for either Meryl Silverman or Robert Witte? All right. I see one from Ray Gunthorp, Gunthorp Farms.

Does STEC testing volumes in FSIS establishments mirror Salmonella testing, 17K in large plants, 173K in small plants and 105K tests in very small plants from 1998 to 2013? Does the testing frequency represent the industry? Would it do intact testing coincide?

MR. WITTE: So I can touch on that, I guess,

briefly. So yeah, they mirror each other in the fact that right now ground beef samples are co-analyzed so one sample is collected and it's analyzed for STEC and Salmonella at the same time so when we collect a -- sample it gets both analyses. In terms of the number, I'd have to double check on, you know, the timeframe and then breakdown by HACCP size.

But right now it's volume based, based on what, you know, the volume that is output from that establishment under each eligible sampling project.

So we sample before the non-intact process, so trimming and other raw ground beef components, and then we sample the product that comes out of the grinder, so ground beef. And so, you know, based on what that establishment produces on a volume scale is what that, you know, establishment is eligible for.

Not every establishment reaches the max every month but, you know, our numbers are based on a volume measurement. I'd have to double check in terms of exact numbers if that's, you know, before that date range for the last whatever, 15 years and something like that. So if that's needed I can -- we can circle back on that and provide that to you later.

MS. EDELSTEIN: And just to follow up so last part of that question, the new intact testing we

haven't made a decision yet so I don't think we can answer that question yet.

MS. GREEN: Thank you, Rachel. We have a few minutes left before we break for lunch. Are there any other questions or any additional questions?

MS. EDELSTEIN: There was a question above about bench trim. Did we answer that one?

MS. GREEN: Would that be explain the MT testing process for bench trim?

MS. EDELSTEIN: Yeah, that one.

MS. GREEN: Okay. Well, Sherri Williams was asking can you explain the MT testing process for bench trim? What does it mean? Why is it done, et cetera?

MR. WITTE: I can touch on that, Rachel, unless you want to. So bench trim, it's a phrase we use to describe that sampling project. So the idea here is this bench trim sampling occurs at a federal establishment. So a federal establishment is say a say a slaughter -- let's just start from the beginning.

A slaughter establishment produces products intended for intact use and products intended for non-intact use. Those products that are intended for non-intact use or when the intended use is not clear are

sampled at that slaughter establishment.

As we've described here there are certain situations where these primals are -- or any other product intended for intact use goes out into commerce, those products aren't eligible for sampling. So what happens if another establishment buys that product and wants to make ground beef?

That's where the bench trim sampling project comes in. That only applies to federal establishments, you know, that have HACPP plans and have, you know -- that obviously go through the HACCP process to implement their controls as they see fit, you know, based on the situation. And then those products are then eligible at the downstream processor -- processing establishment that makes, you know, non-intact products out of those products the supplier originally intended for intact use. So it's kind of a relationship between establishment one and establishment two.

There's no bench trim sampling in retailers. That's -- the ground beef sampling, the 500 a year that we do, the sampling we do at retail there is no bench trim. Did that help, Sherri?

MS. WILLIAMS: Yes, Thank you.

MS. GREEN: Thank you, all. Seemed like we had a lot of interesting questions for both Meryl and

Robert.

Right now, we'll go ahead and break for lunch and I'm going to ask the event host to post the link for not only the panelists but also the attendees and the respective chat sessions so they can log back in after lunch. We will resume at 1:15 p.m.

(Off the record at 12:08 p.m.)

(On the record at 1:15 p.m.)

AUTOMATED RECORDING: Your line is now unmuted.

AT&T EVENT PRODUCER: Welcome, and thank you for joining today's conference, National Advisory Committee on Meat and Poultry Inspection Public Meeting.

My name is Victor Almeida, and I'll be your event producer for this conference. Before we begin, please ensure you have opened the chat panel by using the associated icons located at the bottom of your screen.

If you require technical assistance, please reach out to the event producer. All audio lines have been muted until the Q&A portion of the call. We'll give instructions on how to ask a question at this time.

To submit a written question, select all

panelists from the dropdown menu in the chat panel, enter your question in the message box provided and then send.

With that, I'll turn the call over to the moderator, Val Green.

MS. GREEN: Thank you, Victor. Good afternoon, everyone. We'll go ahead and resume the meeting. And for the record, I will go through the two charges in their respective subcommittee members.

But before I do, I'd like to remind you there's a slight modification to the agenda. We did not receive any requests for public comment, so we'll extend the deliberation period to 4:45 p.m. At that time, we'll reconvene for the day's wrap-up.

I would also like to note that the deliberations are open to the public. Members of the public may jury either subcommittee. Next slide.

Subcommittee 1: this committee will focus on the validation of ready-to-eat, shelf-stable, multi-hurdle lethality treatments.

On this subcommittee, we'll have Jennifer Eberly, Tina Rendon, Patricia Curtis, William Battle, Kimberly Rice, Curtis Knipe, Amilton De Mello, Thomas Gremillion, and Greg Gunthorp.

Subcommittee 1 will stay on the main line, so there's no need to log off and dial into another web conference. Again, Subcommittee 1 will stay on the main event line. Next slide.

Subcommittee 2 will focus on FSIS testing of boxed-beef primal and sub-primal products for Shiga toxin-producing E. coli.

On this committee, we'll have Jimara Avery -- sorry, Jimmy Avery, Tina Conklin, Casey Gallimore, Sherri Williams, James Jenkins, Joseph Harris, Byron Williams, Sarah Sorscher, Denise Perry, and Alice Johnson.

Subcommittee 2 will log off the main event line and join using the instructions provided in the email message that I sent earlier. Members of the public may join Subcommittee 2 by following the breakout instructions in the chat message.

Are there any questions or comments before you break into the groups? Please press #2 if you're a member of the audience and you have a question. Committee members may unmute your phone if you have a question.

MS. EDELSTEIN: Sorry, Val. This is Rachel. If the public joins, are they -- they're just -- they're in listen-only mode, right?

MS. GREEN: That's correct. The public will be in listen-only mode. Anyone have any comments?

AT&T EVENT PRODUCER: I don't see any questions coming in through the phone.

MS. GREEN: Thank you, Victor. So, at this time, Subcommittee 1, please remain on the line so you can begin your deliberations. And, Subcommittee 2, you can log off this main event line and follow the instructions to log into the Subcommittee Deliberations line.

So, Subcommittee 1, while folks are dialing off, before getting started, what I'd like to do is introduce the subcommittee designated federal official, and that's April Regonlinski. And I'll go ahead and turn it over to April.

MS. REGONLINSKI: Hi, I'm April Regonlinski with the Office of Policy and Program Development in FSIS, and I'm the designated federal officer for this subcommittee today.

I think we're going to start with can each of the subcommittee members please reintroduce themselves for the record today?

MR. GREMILLION: This is Thomas Gremillion with Consumer Federation of America.

MS. RENDON: Tina Rendon with Pilgrim's Pride Corporation.

DR. CURTIS: This is Pat Curtis. I'm with North Carolina State University.

MS. RICE: Kim Rice, Rose Acre Farms.

DR. KNIPE: Lynn Knipe, Ohio State University.

DR. DE MELLO: This is Amilton De Mello, University of Nevada, Reno.

DR. EBERLY: Jennifer Eberly, Maine Department of Agriculture, Conservation, and Forestry.

MR. GUNTHORP: Greg Gunthorp, Gunthorp Farms. I don't see anything on my screen though, don't know whether I'm supposed to.

MS. REGONLINSKI: That's fine. I think we're just waiting for Tina.

MS. RENDON: Tina Rendon is here. Can you hear me okay?

MS. REGONLINSKI: Yes, I can. Thank you. I think that is all the members of the subcommittee. Is there anyone else?

(No response.)

MS. REGONLINSKI: So, I'm now going to turn it over to the subcommittee to select a chairperson

before you start discussing the charge. Please remember to identify yourselves for the record whenever you speak.

DR. EBERLY: This is Dr. Eberly in Maine. I'd like to nominate Dr. Curtis as I saw from her profile that she did serve on this committee before.

MS. RICE: This is Kim Rice. I'll second that.

DR. CURTIS: Thanks, Kim.

MS. RICE: I knew you'd love that.

DR. CURTIS: Believe me, I'd -- I'm more than willing for someone else to do it, if they would like. No, I would be happy to try to lead the group.

So, April, are we going to be voting or are we -- hopefully --

MS. REGONLINSKI: Sure. That is probably the best thing to do. So, can everyone please vote? Just say yes with your name, if you vote that Pat Curtis should be the chairperson. Thanks.

MS. RENDON: Tina Rendon, yes.

MS. RICE: Kim Rice, yes.

DR. EBERLY: Jennifer Eberly votes yes.

DR. KNIPE: Lynn Knipe, yes.

MR. GUNTHORP: Greg Gunthorp, yes.

(Audio distortion.)

MS. REGONLINSKI: Hello?

DR. DE MELLO: It's very hard to hear you. Your voice is breaking up a little.

MR. GREMILLION: Thomas Gremillion -- I vote yes.

MS. REGONLINSKI: Okay, Pat, so I'm going to turn it over to you.

DR. CURTIS: Okay, this is --

MS. SILVERMAN: We're on the subcommittee deliberations.

DR. CURTIS: Okay, for clarification, I'm leading the discussion. Somebody else is taking the notes. Is this correct?

MS. REGONLINSKI: Yes. That's correct.

DR. CURTIS: Okay. And then Carrie Clark should be taking the notes. It should be starting to show up on your screen.

MS. SILVERMAN: Okay. Yes. And this is Meryl Silverman. I am here to -- if you have any -- if the committee has any questions. And also, I know there was a question earlier about the guideline, and although we did prepare that to share today, I am available to answer any questions about what the agency plans to include in it.

DR. CURTIS: Okay, and we should get through both of these questions today? Or what is the plan for today and tomorrow? Can you clarify that for us?

MS. SILVERMAN: Yes. So, you have until 4:45 for the deliberations today. But if you need more time and need to continue into tomorrow, please let me know at 4:15, and I will let Val Green know, and she can schedule time for tomorrow morning to wrap up.

DR. CURTIS: Okay, thank you. So, I'm going to just walk --

MS. SILVERMAN: And then Carrie -- and then, I'm going to say, Carrie Clark will be taking notes and will help you write up the report from the subcommittee which is -- it will be shown on the screen. So, you can direct things to her if you want her to make changes or anything else like that.

DR. CURTIS: Okay, and that's what we're presenting on this afternoon?

MS. SILVERMAN: You would be presenting it tomorrow, but you could finish this afternoon.

DR. CURTIS: Okay. Just wanted to clarify. Okay, so let's open the floor for discussion. We can start with our first question about the actions

that FSIS should take when it's determined that an establishment lacks scientific support for that lethality treatment of a fermented, salt-cured or dried product.

As we can see on the screen, that they had several options, but there may be other options. I'll just put that to the floor for discussion of the thoughts of committee.

MR. GREMILLION: Hi, this is Thomas Gremillion, Consumer Federation of America. I guess I didn't really understand the presentation. I mean, I understand that, when this happens now is when FSIS determines that an establishment lacks scientific support, they take enforcement action pursuant to the regulations that are there, I guess, stagewise, from A to Z.

And what I didn't really gather was what's wrong with the status quo. You know, if this is -- there's an outbreak in 2011. I didn't hear, really, that small processors or some producers are having a tough time responding to the enforcement actions.

So, I guess I just wanted to know kind of what are we -- what problem are we trying to fix here?

MS. SILVERMAN: Yes, this is Meryl

Silverman. So, I can tell you from FSIS's perspective and then hopefully turn it to the committee.

So, as I mentioned, you know, in order for an establishment to come into compliance with those regulations, they would need to be able to provide scientific support. And so what I was trying to address is that it's very hard for them to readily turn to what's free and available, like a journal article or guidelines, and come up with that, because it is either not -- it doesn't exist or it doesn't match what they're actually trying to do.

And so, then that really leaves them with one option, which is conducting a proprietary challenge study where they go to a private lab or a university and they get a study conducted to match their exact process.

I think one key point I say that -- share is that the problem with that is that it's very costly. So, at a minimum, I've seen much less than $10,000 and it can range to $30,000 or more. So that is a challenge for small and very small establishments to afford. So that's really the main issue we see from SSI.

DR. CURTIS: And is the issue that these --

oh, I'm sorry.

DR. DE MELLO: Yes, this is Amilton De Mello. So, in my understanding, so -- 1994 outbreak of E. coli, I'm assuming that all of these establishments are federally inspected. Is that correct?

DR. CURTIS: This can be done under a retail exemption, you know, if they meet the requirements, but we're focused today on FSIS establishments.

DR. DE MELLO: Okay. In order to obtain, you know, your asset is there every day -- or inspectors are there every day you do need to have your HACCP validated. You need to have your validations in place when you do any type of his product.

So, I am in the same position of a former fellow asked, you know, I'm quite -- I'm trying to quite understand, regarding the scientific board, in order to have your support documentation or HACCP, you do need to have scientific support. So, that's what I struggle to understand, what is the target here?

MS. RICE: So, my question is -- this is Kim Rice with Rose Acre Farm. So is the issue that

these different or smaller niche artisanal sausages are not referenced in current scientific data that exist and/or they may have a different, slightly different formulation or fat content or there's some attribute that does not make them an apples to apples to the current research that's out there that supports the semi-dried fermented sausage products, and that's the rub?

And so most of them are small processors who, as you said, don't have the financial wherewithal to pay for these validation studies to validate their formula or their specific process because it doesn't match up exactly to current data that's available and free?

DR. CURTIS: Yes. So, it's both. So, in some cases, for some products, there is not a single study available that would be sufficient for validation. In other cases, there are a few there.

They are, but the processor just does something different, like you indicated. They have a different formulation, a different diameter, different temperature, and so the scientific support would not match from a validation standpoint.

And then to the earlier questions, I mean, definitely we see with new establishments it can be

a challenge like a barrier to entry to start producing these products under inspection.

If the scientific support doesn't like this, again, that means leading to commission a challenge study. And then, you know, it's only several years ago that we put out our validation guidelines.

And so we do still find, when an EIO does a food safety assessment of the establishment, just doesn't have scientific support on file. Or it may be on file, but it's really not a match to the process.

MS. RICE: So there are probably some smarter, very smarter people than me on the phone, but ultimately the finished product has certain attributes: pH, water activity, fat content. Does it really matter whether the formulation or the species is the same?

Does it matter, necessarily, how it got there? And I know that the answer for some bacteria is, yes, it does matter -- toxin formation and whatnot.

But ultimately, if we keep it simple, does it matter that it's not apples to apples if the ultimate finished product doesn't support the growth

or won't support the growth over time?

DR. DE MELLO: Yeah, this is Amilton. On the top of this comment, right, so even the amount of variability that we have in these broad-based ones, what you are thinking about and having specific research that validates that is specific broad, the only way to obtain that is to have internal validation by using a third party.

MS. RICE: Which then gets to the financial perspective. You know, these --

DR. DE MELLO: That's right.

MS. RICE: -- small processors don't have 30 to 50 grand, depending on who you're talking to, to validate a process.

DR. DE MELLO: Yep, I agree with that.

MS. SILVERMAN: So, has --

MS. RICE: And --

MS. SILVERMAN: I'm sorry. I was just --

MS. RICE: I'm sorry, I just --

MS. SILVERMAN: Go ahead.

MS. RICE: Go ahead.

MS. SILVERMAN: Well, I was going to say that they also generally are not part of a larger trade association that does do this kind of research. So that's all I was going to say, so go

ahead.

MS. RICE: So, there hasn't been that many outbreaks from this product. Correct, from what the presentation said?

So, the people that are producing this product now, are they using one of these, are they -- do they typically collect articles that have portions of, you know, like Option C where they have documents that support part of what they're doing?

Or do you know what the producers that are doing that currently actually have? Do they fall and did any of these areas that they're trying -- that we're looking at as options?

DR. CURTIS: I don't --

MR. GUNTHORP: Well, actually, it’s a lot of --

DR. CURTIS: Go ahead.

MR. GUNTHORP: I deal with a lot of very small processors here in Ohio, and several of them are the artisanal processors. And so, I dealt with this and we tried to get validation studies from the starter culture companies.

Some are willing to provide information. Jim Backus, who some of you might know, has told me he works very closely, in Florida, with the Diabel

(ph.) company. And he says all of these starter cultures have been validated.

He said that data is out there. The problem is the data that they have is usually tied to when they've done a challenge study for a large company. So, they won't give everything that the small processor needs.

So, that has been a challenge. So now the other thing that -- that's why I raised the question earlier with Meryl, was who was this starter culture company that has done a more complete study or presented more of the data.

And so, we were visiting about it. But that's -- so I think that's what these companies have been using just to kind of get by. And I'll be honest with you, I've had several in Ohio. I did everything I could to help them find -- and there were some of these companies said, yeah, we'll send it to you, we'll send it to you, and they never did.

And I was actually telling the small companies, if your starter culture company won't provide you with the validation, find another company.

And they -- it may actually be working because I just got word back yesterday from a

company here in Ohio, in Columbus that, he said he thought most of the people were actually using -- most of these small companies who are using the Chr. Hansen cultures.

And that's the companies that Meryl had mentioned, was -- had done the more complete study. But I just -- I think that's the challenge, is they they are -- and the other challenge we get into, too, I will put this out and maybe you already know this.

A lot of these people have a culinary background and food safety is not necessarily their highest priority. It's the flavors and the experience and that sort of thing, and so that's another challenge that I'm sure inspection has, that they just haven't been brought up with quite as much of the microbiology and the food safety. So, I'll stop.

DR. KNIPE: Yes, I have a question for you. So, I'm assuming that this small processors are federally inspected too, right? Are these federally inspected is --

MR. GUNTHORP: Can you repeat that?

DR. DE MELLO: Yeah, are these -- are your small processors in Ohio federally inspected? I

mean, do you have USDA inspections?

MR. GUNTHORP: That was before, and I was going to mention it earlier. We also have state inspections that one of these companies --

DR. DE MELLO: Yes.

MR. GUNTHORP: One of the companies that has probably the most successful here, it switched to federal. And that due was a totally different problem. But they are now operating under federal inspection.

DR. DE MELLO: Because one of the main one requirements in order to put together a HACCP plan is you have to -- part -- in addition, you do need to have letters of a guarantee of the product.

So, if somebody is using a culture, right, that culture should have letters of guarantee. And, like you said, I mean, they should have a validation document that they run with somebody else.

So, these guys, they do have money. These small processors, they don't, right. But the sellers usually do have it. That's one of the concerns that I have, because it seems that the major gap, right. It's understanding what is documentation's we need. Because this --

MS. SILVERMAN: But if you look --

DR. DE MELLO: Go ahead, sorry.

MS. SILVERMAN: Well, no, go ahead, Amilton. I apologize.

DR. DE MELLO: No, no. And it's because we do a lot of things here. You know, I'm director of the only HACCP plan in Nevada who does these things because we're more a cow-calf state.

And we went through all these over the last four or five years. And we did our current validations. We did everything. And we have the small producers working exactly the same thing with you guys and crew.

What needs to be their HACCP plan, so there is significant amount of ways that we can see if this works or not. When you submit your label application, right, you have all the details right there. You know, these can be -- usually it's tracked by USDA.

And they say, hey, what do you need here in order to approve your label? So, if this happens here, it happens with all of us. My major concern is that I don't think that they really -- there's like this gap is actually on the consumer -- on the small producers.

It's just -- it is how we can reorient it

to, you know, have everything in place to make sure that these producers of safe products are safe products. I'm not sure if I was clear on that.

DR. CURTIS: Yeah, so if you look at what they've put together on Slide 16, from my experience, both with non-intact beef and then poultry slaughter and parts, and using antimicrobials, one of the things that we would run up against is if we were using -- let's say, on poultry slaughter antimicrobials, we were using a certain microbial we were using the supplier's data, right, their research that we were using a different novel configuration or a different a different concept -- something was different from the original research, we were told multiple times that we had to go back and redo the work.

Because the --

DR. DE MELLO: Sorry, Slide 14.

DR. CURTIS: Yes. I apologize. Slide 14. Yes. Sorry. Because we were you know, we were diverting or going -- moving away from the way the work was done originally. So, my sense from this conversation, from the agency's perspective, is there are every single step in the process.

And if you look at this list, that's what

it looks like. They are looking for you to have data or research or back for why you do literally everything you do. So --

DR. DE MELLO: It requires -- this requires individual validation then.

MS. SILVERMAN: Yes, so this is Meryl. We -- hold on. So, what I -- yeah.

COURT REPORTER: Can -- I'm sorry. Can the participants hear me?

MS. SILVERMAN: -- to finish the thought, process is we didn't necessarily go back and do that. What we did was we were able to show that what was really important was coverage and contact, time and concentration, right.

And so that even though we weren't using the same number of novels or the same configuration of novels, we were still getting the contact and the contact time.

And so, there -- you have to be able to take the research, apply it to your facility and make it -- make the argument that what you're doing is in line with the original research. And my sense is that the small guys aren't going to know how to do that.

As someone just made the point, both of

these folks are from a culinary background. They're not from a science background at all.

DR. CURTIS: And that's, I think, that when they change something from a culinary standpoint, it could impact the -- something. It may not impact the starter culture, but it may affect something else that would impact food safety.

MS. SILVERMAN: Correct. And then --

COURT REPORTERS: Can the speakers hear me?

MS. SILVERMAN: -- they may not. But they have to be able to defend that it doesn't, right, which goes back to the ultimate, the end-product and the characteristics of that product that either don't support the growth or you've got that five log kill through another method or five log or two log.

I was getting so confused when we going through it. I'm not sure what log you're supposed to get. But yeah.

DR. DE MELLO: Well, if you have a product, contact leader is five log of someone else, you are really in trouble because five log is a lot, right? And that requires five log reduction, so -- for RD.

So, there's a lot of things that need to be discussed here.

DR. EBERLY: So, this is -- sorry, this is

-- is it okay or --

DR. DE MELLO: Go ahead.

DR. EBERLY: So, this is Dr. Eberly in Maine. So, I am basically a regulator, right? I'm just FSIS, but on the state level.

So, I guess I just wanted to make a couple of comments briefly. I see the quandary here for FSIS because I have -- I fact the same thing. You know, I get this just a pile of journal articles that kind of support it, but not quite.

But there's nothing else out there. And I feel for my processors, all of which are small processors, because it's very difficult for them. They don't have the financial resources to do their own studies.

And, you know, their companies are very proprietary and not willing to release data that they have -- somebody else has done and paid for in order to help them.

I guess my feeling is that, you know, I'm not -- looking at these choices here, I'm not super keen on, you know, B, just letting them do whatever. But I'm also not particularly keen on A, which is basically shutting down anybody who doesn't have $50,000 to do a channel study because -- for two

reasons.

First of all, it seems a little unfair, right. It seems like we're getting -- I mean, one, this large industry -- largest slaughterhouses who have more money, right, will be able to advance in the marketplace as opposed to a smaller facility.

And not that their not, you know, the thing that's ruining all our lives at the moment, but COVID has kind of just demonstrated that small processors are a really important part of the makeup of the meat industry.

When they were this year with a larger facility, there was some smaller facilities that were the ones who have got planned and still are booked until next year. Oh, -- well passed next year.

So, I do you think there is some -- the agency perhaps needs to be a little more flexible when it comes to accepting journal articles that maybe they aren't, as someone else said previously, maybe it wasn't the exact novel, right?

I'm not saying no to completely disregard changes. I mean, there's -- some changes are significant. But I do think there needs to be some flexibility in what USDA is going to exercise and

it's actually going to fund studies to help these, you know, publicly funded studies, right, that anybody can access.

I think in the meantime, they should consider at least doing case by case, you know, looking at what somebody said, does the novel matter? Does the temperature matter? Does the whatever matter? So, I'm done -- sorry.

COURT REPORTERS: I'm sorry to interrupt, but if all the speakers on the line could please state your name each time you speak, for the record, please? Thank you.

MR. GUNTHORP: This is Greg Gunthorp.

MS. SILVERMAN: Hi, this is -- go ahead.

MR. GUNTHORP: Oh, thank you. I'm a small farmer in a very small processor in Indiana, Gunthorp Farms. We actually produce the dried product. We do a -- prosciutto ham. Don't have our first ones coming out of our cave yet, but it should be around Christmas time.

We are fortunate in that in our product we found a scientific support paper that as long as we age for more than 206 days and use one of the prior trichina methods in 9 CFR 318.10 that our process will be a validated process. So, we're fortunate in

that regard.

I would say to talk about what the problem is for me as a processer's perspective and knowing many of the other federally-inspected establishments, because I would guess that it's less than 25 in the whole country that are USDA inspected establishments that produce dry, cured charcuterie products.

And, I mean, I think I know most of them. I would say that the problem, in my opinion, from a processor's standpoint, is first and foremost enforcement actions are largely, over the years, have been on beef and not being able to substantiate E. coli 0157 log reductions.

And then the second thing that I would say is that there's a lack of consistency or continuity across districts and how these enforcement actions have taken place in the past. And I know, for a fact, that some support in some districts has been adequate while it's gotten other plants on suspended.

And I know from my personal experience on dealing with other issues that I know that the higher up that we get in USDA, we've got a couple of EIOs in our district that are hurt with. But in

general, as I get to the high levels of risk management, they are very, very knowledgeable and very, very good at making determinations at that level.

And I would recommend that as fewer establishments actually produce these products, that perhaps these kind of decisions should be made above the EIO level and perhaps even made above the district level so that there's continuity and so that there's some real solid decision making in these processes.

MS. RENDON: So, this is Tina Rendon. And I would agree with that statement in the sense that, you know, continuity as far as the guidance on how to enforce it. And I think that's gone into that purpose behind doing a guidance document.

That way that the industry has that to fallback gone to use as their justification and their systems help them support it. Going off what Dr. Eberly was talking about, the Option C, doing more mixing, matching of, you know, journal articles, scientific studies such as that, I feel would be the best way in order to make this happen.

And then going off of what Kim said, allowing that flexibility -- or both of them said

that -- as far as allowing the flexibility on applying even those journal articles.

But that thing, the challenge I think most people are going to run into is finding those -- that support. So, making that available through the guidance document would definitely be a tremendous help.

One other thought is kind of like the process. And I know this has been backed by like the Meat Institute, NAMI and the Agency for Appendix A. I know that the lethality, Appendix A has been a big, long process as far as trying to get that published and forced and a call for support on scientific help.

You know, I don't know if that's feasible in the sense of an agency putting it out there, scientific help, you know, a call for that, for the universities. I know we've got a couple that are represented here.

I know you in Ohio have had some work. I don't know what kind of studies that you have that would be available to the public or if it's all proprietary or what assistance can be provided there. But that's one way I would suggest that we couldn't (ph.) go about getting more scientific

studies that are publicly available.

DR. CURTIS: Pat Curtis. Would you, in looking at those scientific studies, do you think that the agency should provide the key criteria that you're looking -- I'm thinking if they're small companies, as I don't have the expertise of all culinary, will they know what are the key components that they're looking for scientific support for?

Is it the pH? Is it temperature or is it time? You know, providing them some guidance in that area.

DR. KNIPE: Yeah, this is Lynn from Ohio State. I think these small culinary types are learning, and I just think it's not been in their nature to focus as much on the safety as the quality and whatnot.

But another thought I had, I remember when we had the issue of jerky and destroying salmonella before we dried the product. And Wisconsin came out with -- it was a pretty extensive study, but my first thought was we're going to tell these small processors that this is the major research we have for them to follow.

And we didn't tell them they had to do it this way, but before I knew it, almost all of our --

and we've got a couple hundred very small processors. They were all following the Wisconsin study. They were adapting their jerky to make it to meet that requirement.

So, I'm very much against requiring try and expect these very small companies to do the challenge studies themselves. But I am wondering if it would be possible -- I know they wouldn't like it, but if we could set up -- and I think that's what Pat was getting at, was maybe setting up some requirements.

And as we heard earlier that there's more safety with the higher temperature fermentation, that right there a lot of these culinary people are going to say, no, I want to do it the European way and I want to ferment at lower temperatures.

But if the data's not there, I don't know what you would think about setting up some parameters and then saying this is what we have and adapt your process to that.

MR. GREMILLION: Hi, this is Thomas Gremillion, Consumer Federation of America. That makes a lot of sense to me. And, yeah, I was going to ask, are there templates available to these processors to kind of, you know, some pretty get-

away that they can meet the requirements.

I wanted to -- I'm confused now by what Dr. Knipe has said. It sounds like there's a lot of these small processors. And Greg had mentioned, you know, there's just a handful.

I definitely agree too that it doesn't seem like there should be variation from district to district on those. But I wanted to -- maybe the FSIS staff can clarify, how many regulated entities are we talking about here? I mean, how many federal inspected producers are we talking about?

MS. SILVERMAN: Yes, so this is Meryl Silverman. I can give you a rough idea from the data within the public health information system.

So, we do know, so at least now, it was about a year ago there were about 150 establishments that had at least one ready-to-at fermented meat or poultry product. There were about a hundred that had at least one salt-cured meat or poultry product.

And then the challenge of our data is that there there's over 500 that have dried meat. But that would include something like biltong, which is a South African air-dried beef strips. But it could also include jerky. So that data is not as clear which jerky's typically cooked and doesn't fit into

what we're looking at.

But again, about 150 establishments with fermented products in their profile, a hundred with salt-cured, several hundred with dried.

DR. KNIPE: This is Lynn Knipe again, just to follow up. When I was talking about having a couple hundred very small processors, most of them are only making jerky. What --as far as companies that are making fermented dried shelf, stable products without heat, we've only got two or three. And so that's the difference.

MS. SILVERMAN: Yeah, this is Meryl. Just one other thing, if it would give context, so there's a little over 2,000 establishments that make ready-to-eat products in general. And then, you know, there's a few hundred that have these products in their profile.

DR. EBERLY: This is Jennifer Eberly. I have a question for Meryl. If we considered -- I guess I don't know what options it is now, Option T, where this really sounds like what we want is a guidance, clearly, is what we -- we all want a guidance.

And I understand that the problem on you all's end is that you don't have enough information

to issue a guidance. But, as a stop gap, if we considered, as Lynn suggested perhaps one entity. I don't know if WIMS (ph.) or whomever.

If one entity was established to evaluate, you know, does this journal article meet, even though it's not perfect, does it meet whatever -- is that something that the agency would be able to do? Is that even an option?

MS. SILVERMAN: Maybe April could also weigh in. I don't think we -- you should rule it out as a recommendation. But, yeah, any -- I think it would be really important that the committee does lean toward this option, like the guidance you can give advice FSIS as to how we would do this or be helpful, to be -- to make consistent decisions from establishment to establishment.

I don't know, April, if you have any thoughts also about that recommendation.

MS. REGONLINSKI: This is April. I think. If you will -- the most information you can provide, FSIS with your recommendations, I think, would be the best thing.

And then we would eventually decide what we would do with those recommendations at the end. We don't want to cut off any deliberations or try to

point you in any directions here.

MS. SILVERMAN: So, does the committee have any other suggestions on more information surrounding the idea of that suggestion, of getting someone to evaluate, you know, to provide for one entity to evaluate establishment support?

MS. RENDON: So, this is Tina Rendon. Is it possible or feasible or whatever to submit articles, scientific support such as that to ask FSIS for review or is that -- are we talking about a different type of entity?

DR. EBERLY: This is Dr. Eberly. I really just want to comment that, I hate to say this, but sometimes I send the questions to ask FSIS, and if I don't like the answer, I just send the question again until I get the answer that I want. So, I just wanted to throw it out there that this is sometimes a little problematic.

MS. REGONLINSKI: So, I guess the bet with that in mind, then what are the criteria that we would want to add as a portion of this recommendation?

MR. GREMILLION: Hi, this is Thomas Gremillion. All right, I'd like to understand the allowed establishments the test and hold

indefinitely option. Could you elaborate on that, what that would mean and like why that would be attractive to some of these producers?

MS. SILVERMAN: So, this is Meryl Silverman. At least I can say for FSIS, so we did discuss in some of our documents how establishments may, while they're gathering their scientific support test, and hold the finished product. And we typically recommend 10 to 15 samples per lot to be tested for at least one pathogen, for just Salmonella.

And so that would be in lieu of having scientific support. So instead of putting the upfront cost to a challenge, establishments can pay the cost per lot to have it tested while they can gather support. So, this option here was -- it was originally discussed in the 90s before HACCP was implemented.

And so that blue ribbon task force was, in lieu of gathering scientific support, establishments could support each lot as safe by collecting samples of it and having the finished product tested.

MR. GUNTHORP: Would that -- did this step require any log or reduction -- sorry, this is Greg, Gunthorp Farms. Did that step will require any log

reduction support in the process at all?

MS. SILVERMAN: No, not from the original blue ribbon task force. We have taken the position that the -- that's not consistent with HACCP that establishments do need to show some amount of reduction and come up with some targets.

It could be the five logs are an alternative. But that's why we wanted to put it to the committee, to see if that's an option should be considered.

MR. GUNTHORP: Because, I mean, that's a relatively inexpensive compared to what you were talking about before, but it's just, like you said, doesn't -- seems extremely contrary to the whole HACCP principle.

MR. GREMILLION: Yeah, this is Thomas Gremillion again. I mean, I see a couple problems with that. Of course, in one you could kill the pathogen that you're -- if you're only testing for salmonella, then E. coli 157 could slip by.

And, two, if you just -- there could be a change in -- or something and you could make your product because -- I mean, yeah, just, it's -- I mean, I wish could just say that, but just kind of that, the last comment, it's really not consistent

with HACCP.

DR. DE MELLO: Another question. This is Amilton De Mello again. So is the requirement, is it a 5.0-log reduction in salmonella and apparently, you're trying to discuss if this can happen in situ, right.

So how does the agency expect to see or an internal validation of whatever it wants to do, a 5.0-log reduction? You know, how often do you have 5.0-log of salmonella in these products?

MS. SILVERMAN: Yeah, so the 5.0-log reduction comes from a risk assessment that we have performed and typically our recommendations take into account baseline level pathogens in the product, but also allows for a safety margin.

And so NACMPI recommends for a target, lethality targets to have at least a two-log safety margin.

MS. RICE: So once --

DR. DE MELLO: Yeah, this is Amilton again.

MS. RICE: Sorry, this is Kim Rice. I just wanted to add on to that, Amilton. So once a process has been validated, then it will give a 5.0-log reduction. You don't have to do that, that study again and again and again.

You just have to show that you're meeting the requirements or the parameters of that study. That's all you have to do. You don't have to do the testing over and over and over again.

DR. DE MELLO: No, no, I understand that point. What I question, myself, is what is the -- suppose that they have salmonella contamination in these products, right. That's thinking about worst-case scenario.

How often that a concentration reaches 5.0-log? That's the first thing that I want to know. Yeah, I got it. Once you proved once, I understand that. But I mean, you're requiring a 5.0-log reduction basis risk assessment.

What is the common log contamination that we have when a product is contaminated salmonella? Can somebody answer that question for me?

MS. SILVERMAN: It's going to depend on the raw material, right?

DR. DE MELLO: Yeah. But how much? That's the parameter -- so to reach 5.0-log of salmonella is a lot. So, you know, I would like to know, do we come up with this parameter as a 5.0-log reduction based on the risk assessed.

If you go back and evaluate all the

products that were contaminated salmonella, what is the average of the contamination load?

MR. GUNTHORP: Without temperature abuse -- this is Greg -- without temperature abuse, I wouldn't think that USDA-inspected products should see more than a one or two-log reduction. Or one or two logs of salmonella ever, except for without temperature, so.

DR. DE MELLO: That's my point. Thank you.

MS. RICE: Pat, this is Kim Rice. Back to your original question, I think the hesitancy that I have is that we're being asked Question 1 and then Question 2. I think we should be Question 2 and then answer Question 1 because, clearly, there's a hole, right, in the information available to anyone to use.

And so, what are the needs, right, and how difficult would it be to fill those holes and then, in the meantime, how should FSIS handle it? Because, you know, the regulatory person in me is, everybody should be playing by the same rules. Period.

So, the validation requirements are the validation requirements. However, there's a reality that there's this group of products and this

consumer demand for these products that smaller, more culinary type folks are trying to fill that need. And that hole needs to be filled up in the meantime.

So, I'm reluctant or are at a loss as to what to -- how to answer Question 1 at this point.

DR. CURTIS: Well, if you like, we can move to Question 2 and come back to Question 1 after we've addressed Question 2.

So, Question 2 is, how can FSIS assist industry gather gathering scientific support and facilitate filling research gaps, even though it is not a research funding organization? So, let's address that and then we can go back if there's additional things they want to have going afterwards.

DR. EBERLY: This is Dr. Eberly. I understand the guidance is not done yet. Does FSIS have available a list of all of the journal articles that are presently accepted by the agency available for people to look at?

DR. CURTIS: Yes, at least for the guideline, we did do a comprehensive literature review. We don't have that list available, but it would include a list of journal articles by product

type, is the intention.

DR. EBERLY: Who would -- sorry, the is Dr. Eberly again. So, based on the list that you have now, would you be able to come up with a list of gaps of journal articles that we need?

MS. SILVERMAN: This is Meryl Silverman. Yes, I think so. I think we can show through that where there lacks scientific research.

MS. RICE: This is Kim Rice. And does it make sense, those gaps? Are they simply because the formulas don't match up or the exact process doesn't match up? And is there a way to look at or have someone that's an expert in that particular area or that particular organism look at it and say, yeah, but the end-product is fine or that doesn't affect the outcome, and we would still have a safe product, even though this isn't an apples to apples comparison? Is there a way to do that?

MS. SILVERMAN: For FSIS, the goal is -- or intention in the guideline is to give some rules of thumb of when parameters can differ.

And that would be acceptable, but I think the way we're currently approaching it, which has been discussed as to leave a lot of potential differences that establishments would need to

support. So that's really where I think the committee's feedback on that Option C could be helpful or also here.

And then again, it's also both, so for some there's not a single article available.

DR. KNIPE: This is Lynn Knipe again and what I question is a lot of the gaps may be more -- a lot of that concern may be more on the drying process because it seems like we've got a lot of data that show how much -- potential we have in fermentation. May not be perfect, but where we may be really lacking is the drying data.

And what I've noticed with the starter culture companies, they may only go out a couple of weeks. And there's also some data to support, once you package the products and you store it and you continue to have lethality.

But Meryl and I had a little offline conversation this morning. And she reminded me of something I had really forgotten, is the diameter of the sausage and how much difference that makes in the dry, the lethality.

And all of the, particularly in artisan companies all have very specific interests in the size of their product. But I think that's where one

of the challenges is. Every time you see a publication, they're not using the right diameter product or whatever for the drying.

And that's one of the challenges, for me sometimes, is kind of overwhelming, where -- how can we develop a study that really fits all these different options?

MR. GUNTHORP: This is Greg again. You know, if we look at the old trichina regulations which are gone now, but USDA did that way back in the day on trichinosis with percentages of salt and also trying times. If you just had that data, you could solve most of it for differences in the salt differences in drying and parameters on pH, water activity, that kind of stuff.

MS. RICE: This is Kim Rice. I don't think that data's is gone. The writers are gone. But the data should -- we should still have. Correct?

MR. GUNTHORP: Correct, but the USDA --

MS. RICE: The FSIS?

MR. GUNTHORP: -- doesn't consider those all those validated process, right? Definitely don't consider them validated against salmonella or listeria because trichinosis is generally easier to control than salmonella or listeria. Just cause you

control trichonisis doesn't necessarily mean you control salmonella.

MS. SILVERMAN: That's correct.

MS. RICE: Yeah.

MR. GUNTHORP: And they're a really good starting point.

DR. CURTIS: We have had a research priority on that idea but, because of the holiday district kind of regulations which are now in guidance for other pathogens.

DR. EBERLY: This is Dr. Eberly. I just had a general question. How difficult is it to determine what is going to determine what is going to be the research priorities?

MS. SILVERMAN: We have an internal review panel that -- from multiple offices that reviews them and change -- and then we typically post them on the website a few times a year.

DR. CURTIS: This is Pat. What else do you do with them? Did they go to ARS? I was asked earlier if they go to MIFA (ph.). Are there -- how do you get them out or what do you anticipate in getting them picked up whereby -- from the agency?

MS. SILVERMAN: Yeah, so as I mentioned earlier, this is Meryl. We should make sure we

share them with MIFA and ARS. I think this just always comes in to ARD, so it's a challenge.

DR. CURTIS: Other ideas on how we might be able to help fill some of these gaps?

MS. RICE: So, this is Kim Rice. So, I think universities like Ohio State and Wisconsin and I think Cornell and it sounds like Nevada, the folks out in Nevada, they're all doing good work with small processors.

My recommendation would be the agency, you know, visit with them and see, you know, basically compare what they've got and if there's any way to utilize what they have to then build out the guidance even more. And I think then getting the guidance is important to the research priorities or the research monies.

I think ARS and MIFA an any of the other sources of funding, I don't know if there's money in, let's say, the rural development group. I can't think of their acronym off the top of my head, but are there monies there that can be moved to do some research to help support these small and very small businesses to develop out those markets some more?

I'm making this up as I go, literally, so those would be my recommendations. But the guidance

itself with what you have, getting that out so that we at least know where there are holes, I don't think we're ever going to be able to do a study or a series of studies that gets literally every gyration of every different type of product out there that somebody could come up with because everybody's always going to want to do the next great thing.

And so, I think if we can get the basics into that guidance document, of here are the four, five, six, however many they are product attributes that are absolutely critical to food safety and here are the things that affect each one of those that you have to take into consideration, and here are the articles that support or don't, I think that's the best way to get to that data and information gap.

DR. CURTIS: This is Pat. One of the things that you might do is get those scientists together that have done research in this area and let them brainstorm as to what they've done among the groups of them and what they what they may know or what they might be able to do to fill some of these gaps, because they may be able to create a multi-state, you know, grant proposal or something that will go after this.

Since they don't ever get together to talk, they would probably never get together to actually do this project. But they may have information from other research was done in some of these areas to answer some of these questions for us.

And for the guidance that you've already researched and know what those articles are, you probably know who those researchers were that you would want to get together. Other ideas to fill the gaps?

MS. RENDON: This is Tina Rendon again. Piggybacking off what the two ladies just said as far as getting together the people that have been involved in research, is it a possibility of this committee or subcommittee to have a working group? Could it organize that charge, you know, to get those people together, to bring forward discussion?

MR. GUNTHORP: Greg Gunthorp here. I think one thing that ought to consider, too, you know, is multiple hurdle approach and the pre and post interventions are acceptable to add to the cumulous log reduction.

So, if somebody's got a study that gets them close to five logs, say a simple vinegar-water rinse the product before they start that, does that

add enough, a page at the end, what packaging and temperature, what other multiple hurdles can be added to existing validated studies?

DR. CURTIS: Got very quiet. Any other ideas?

MS. RENDON: This is Tina Rendon again. I have a question, I would say, for Greg. I believe you said that you actually make one of these products and know other people in the industry that make these products.

Are under any kind of trade organizations for this type of artisanal meat? Maybe you can tap into as far as, you know, bringing forward the scientific studies and, you know, different things that they've done, you know, that maybe if we were to develop a working group or something like that, they can partner with and help lead the charge?

MR. GUNTHORP: You know, I think there's a couple suggestions. The first one, through the Oregon State extension, would be the Niche Meat Processors Assistance Network, which is right down their alley on working along this line.

So then the trade association, I can never remember the exact wording for it. They're based out of Pennsylvania, the small meat processors and

American Meat --

MS. RENDON: AAMP, Association of American Meat Processors.

MR. GUNTHORP: Yeah, AAMP. AAMP does a really good job in this space. Awesome. Yeah, the other thing that I was thinking about the other day that, you know, it goes along with my thought process, that perhaps these decisions should be made at a higher level, is that, in my experience, and I know that of several others, perhaps these decisions should be started by USDA earlier in the process and perhaps they need to reevaluate the role of food safety assessments on these products.

Because virtually all of these products are a very long time in what they take to produce them. And, you know, several of my friends have been involved in enforcement actions, like I said, mostly on beef products that they were trying to produce.

But it almost seems, and maybe it's counter-intuitive to FSIS, but it almost seems like that they should be involved at a higher level, even if it's just the EIOs at the beginning of these processes rather than after the processes are already done.

Like us, you know, we're two-thirds or

three-quarters of the way and producing a ham and we get three inspectors a day at our plant. And I know for a fact that two of them haven't even really looked over our HACCP plan.

And we've had no, you know, guidance or enforcement or, you know, I don't want to say enforcement, but no looking at it by anybody beyond those levels. And, you know, it's seems like it would be simpler before the product was out into commerce to have these arguments and discussions rather than after the product's done and people are eating it.

DR. EBERLY: Hi, Greg. This is Dr. Eberly. I guess I'm a little confused because I wouldn't allow facility to produce a product until they have given me a hazard plan for it that I had approved. So --

MR. GUNTHORP: you know, USDA doesn't --

DR. EBERLY: I guess I'm just --

MR. GUNTHORP: USDA, though, doesn't really approve HACCP plans. Maybe state inspection programs do, but USDA doesn't. You know, we have to have a HACCP plan. But it's -- the process is kind of a little bit convoluted on a ham that takes a year or two on the validation.

You know, the validation on the design of the HACCP plan is relatively simple. But the validation on the actual process going through it, you know, we've already defined our frequency in that it's going to be 12 lots and we're testing five hands for brine concentration.

And we've added an additional hurdle to start with. We actually put two anti-microbial them beforehand. So, you know, we are validating all that, but. You know, I don't want to throw USDA under the bus, but I mean, it's -- they're -- they've not put a lot of effort into it.

And I think, in USDA's defense, these are really and, you know, also in the processor's defense, these are really complex food safety questions on these products, on understanding, you know, interaction between these pathogens and salt levels and moisture levels, water activity levels and pH.

And, you know, and I -- they're typical. You'll understand, but I don't know that their typical line inspection staff understand these. I'm not sure that a lot of the EIOs would even have experience in these areas.

DR. EBERLY: Well, Greg, you give me too

much credit because I'm not sure what I'm just saying it all perfectly either. I do -- I think maybe -- let me clarify what I said.

I don't actually -- I don't necessarily approve -- hello? I don't approve the HACCP plans, but I guess, because it is a small program, that they're saving themselves and getting in trouble by having a look at it before they start producing. So let me clarify that.

MR. GUNTHORP: Yeah, that -- you know, that just doesn't happen with USDA, though. You know, they just come out right and tell you this. They're not your consultants. They're not this. They're not that.

You know, they don't really look it over or -- I mean, the process is just completely different all over the country in that regards too, depending on how you're staffed with the -- you know, in our plant, we're unique in that we're producing these products in a slaughter plant.

So, we have a line inspector, a public health veterinarian, and we run a second shift. So, we have a second shift processing inspectors. So we'd have the opportunity for three inspectors a day to be looking over these HACCP plans.

But, you know, like I said, I don't know that lots of them have had lots of training in drying and cured products and that kind of thing.

DR. EBERLY: Well, I think that's what causes a problem, though, with asking FSIS to be the consultant because you're going to get -- you're only going to get as much knowledge as that person has.

And, you know, I struggle with that myself, because the -- what do you want, right? But that's not that's not my job, because what has happened and with everybody happen is you'll come back later and say what you said it was okay, but now it's not okay. So that's -- I do understand FSIS's --

MR. GUNTHORP: Okay, it's a Catch -- yes.

DR. EBERLY: -- position on this, I guess.

MR. GUNTHORP: Right. I understand it completely, too. It's a Catch-22 because, you know, the little plants lots of times don't have the time and the resources and, you know, the inspector's there and they're asking them questions with the inspectors in a situation that, no matter how they answer, it's not good.

So, I mean, I completely understand the USDA, you know. They're in a different role than

providing the food safety answers. But that's a different thing, in my opinion, than them evaluating a HACCP plan to see whether compliance with 9 CFR 470 requirements, you know, that once you have it designed, rather than, you know, not having somebody at a high enough level to actually be able to sit down and make those decisions before the plant is in an enforcement action, you know, and before people are served product.

DR. EBERLY: So, you're actually able to get your -- move into production without a validated HACCP plan?

MR. GUNTHORP: Well, I mean, I keep coming back to the, you know, these -- and these products and, you know, I've got answers from this Ask FSIS. And these products, you can't validate a plan, you know, and we haven't shipped anything because we haven't produced any product that's ready to go.

But you can't produce a validated product in 90 days when the product has to dry, when you're intending for it to dry for a year.

DR. DE MELLO: This is Amilton De Mello from Nevada. Yeah, I got a little bit confused on an issue about HACCP plans and -- well, first, I think I see all sides, the producer side and the agency

side.

One of the things that we always need to remember, this type of conversation, is that USDA is a regulatory agent. It's not a consultant. So, on of the things that I usually recommend to our producers here is that, you know, we used to be one step ahead of everything.

So, you know, you need to understand that you need to know what you're doing first because there are some regulatory person out there, they're going to check what you are doing.

Now, if you are federally inspected, if you had a USDA in your product, your HACCP must be validated. So, and I -- it comes back to the idea of a small producers like small processors, sometimes they need just to dry or, you know, age a product for a year before having a -- they give us 90 days of validation to validate their HACCP plan.

You know, this is something that the agency needs to understand too. So, how we're going to find out that the closest point for both sides of depends a lot of these, the producer who needs to have the proper technical support to achieve what the regulation is.

And I think that that's what the base of

the discussion, right, how we're going to get that producer knowing that he needs to be one step ahead and he needs to make sure that the product meets the requirement. So, is it viewed, is, I think, we need to move forward.

DR. EBERLY: This is Dr. Eberly --

DR. DE MELLO: Come back to the state, the state inspection, so if you say, well, we do not have a HACCP validation, the state does the HACCP plans.

I don't understand that because if you do have a state inspection, yes. That's your state responsibility. But if you're federally inspected, your HACCP should be actually approved by USDA.

And I understand, most of times the inspector that is there or your supervisor that is there might not understand everything that you're trying to do. You get, like I said, they are regulatory, right. They're going to have to get your HACCP. They're going to look at you and give you an idea at the end of the day, which is their job.

So, I think if that technical information and that the producer needs to have, it's producer responsibility. Now, the question is how expansive

it is and how hard it is. So, I think that that's -- the answer that needs to be -- that's the question that needs to be answered. Sorry, go ahead.

DR. KNIPE: This is Lynn Knipe again. And I like this idea of a working group, and I would be willing to help that if you come to that point.

But I wanted to -- I had another thought a little bit ago, but I accidentally hung up my phone when I was trying to mute it. And I'm wondering if somebody else might have brought it up.

But my question is, maybe more for the people who represent large companies, there's at least one, and I know there's more than one, but I know of at least one company, and I won't mention their name, that's making this product and they had historically gone for a long time.

The president of their company spoke at a a meat conference several years ago. And I went and approached them, and they had a long line of people wanting to talk to them and they gave me their card.

I got a hold of them afterwards to see if they would be willing to share because they've done -- they've paid for these studies. And I was just inquiring if they would be willing to share any of

this with smaller companies as far as validated data, and they said, no.

And I was just curious if anybody -- I remember a time when HACCP first came out that the -- some of the larger companies were taking the stand that safety was not a competitive issue. And they wanted everybody to be helping each other. But I just was curious if anybody has any ideas of how we might encourage some of these large companies to share some of that.

DR. EBERLY: Dr. Eberly. Just to kind of go off of what he said, my question is for Meryl, I guess. Is there a process for making, I don't know, dried, cured salami, pick a product -- are there some processes that have been validated that are public knowledge?

Because I know that, yes, those people who are artisans are not going to want to be the next best thing. But I also know there's plants that would just like to put a salami out and increase their -- they're not so concerned with having the perfect formula.

Are those -- and this is for anybody, actually, because it's not my area of expertise. Are there any methods of making, say, a dry-cured

salami or some other product that USDA has said, this process is validated? I'm just curious, because that's something we could potentially -- I don't. That's my question.

MS. SILVERMAN: Yeah. So, this is Meryl. I can start because it was directed to me. So yes, for some products, there are, at least what you are describing in the form of journal articles.

There isn't like a generic cast up model available right now. But there are journal articles for some products that would support a 5.0-log reduction in salmonella when those parameters are followed. Does that answer your question?

DR. EBERLY: Right. So, I guess what I was just -- what I was thinking of is, in the meantime, while we're waiting for this guidance that people can use to potentially support whatever their specific process is, whether FSIS could publish some of, you know, a compilation of some of these validated practices just for the people.

I don't know if that would be appropriate or not. It's just a thought. But, for the people who just want to be able to produce salami and not have to do a challenge study or, you know, they just want to make a product. And they don't -- they're

willing to follow that recipe?

DR. CURTIS: Other ideas? Not hearing any other ideas for this, is there anything else you want to go back and add to Question 1?

Based on our discussion we've had about Question 2?

MS. REGONLINSKI: I have a question. How much does it cost to do test and hold? I mean, how much, just a ballpark, to do our final lot? If you were doing 10 to 15 samples?

MR. GUNTHORP: This is Greg. We spend $35 a sample for a salmonella test.

DR. EBERLY: This is Dr. Eberly again. So, when you said, I think it was -- someone said 10 to 15 samples. Is it done by how many -- you know, is a lot -- it's a lot of a thousand versus a lot of a hundred?

Is it proportional to the number of salamis, for example, in the lot?

MR. GUNTHORP: I mean, doesn't that come down to a HACCP question and whether or not we can support our frequency? In my HACCP plan, I use, for our number of hams that we're going to test, we use the old trichina regulations, and it requires five hams out of each lot for 12 weeks in a row.

And we only produce 10 hams in a week, so, we're going to tests five of them, half of them. But I didn't want to get into an argument with USDA over whether we could support our testing treatments.

In general, they lower the volume, you're not going to be able to lower the test much because you still have to test a certain number.

MS. RICE: And Greg, is that destructive -- I'm sorry, this is Kim Rice. Is that destructive sampling?

MR. GUNTHORP: Yes, ours will be destructive sampling because we're going to do a brine concentration of the center muscle to show that we have uniform salt concentration and uniform drying. So, yeah, those hams will be destroyed.

MS. RICE: So -- Kim Rice again. So basically, you're losing 50 percent of your production to validate your process?

MR. GUNTHORP: Yeah, for four weeks, we're going to lose -- or for 12 weeks, we're going to lose half of them, so we're going to lose 60 hams.

And then after that, what I was starting to say was, we have to do that four times a year again to be able to show that our process is under

control. So, for the remainder of my life, we'll have 20 hams that we'll destroy.

DR. EBERLY: Hi, Meryl?

MR. GUNTHORP: And that's actually -- oh.

DR. EBERLY: I was just going to say, Meryl, do you have a -- so he's -- it sounds like he's using the trichina regulations to determine his sample size.

Has there been anything published by USDA that would give him a -- you know, do you have any resources to just how many samples of -- or say it was dry-cured salami, how many in the lot would need to be tested?

MS. SILVERMAN: Yes, so typically when we received that question, for example, in Ask FSIS, we recommend using the ICMSF. I'm trying to think of the acronym. But ICMSF sampling plans and, typically. we recommend the cases.

Those are different cases based on the level of work. And we typically recommend either 10 to 15 samples. So that's where that came from. ICMSF. And those do allow for some compositing so that the actual number of samples analyzed by the lab can be fewer, but they're not relative to the lab size, so that would be 10 to 15 samples,

regardless of the lot size.

MR. GUNTHORP: Yeah, that's where they said that, you know, in the -- to do the batter testing and then use a process that only got a two-log reduction. That's where it's really, really prohibitive for somebody that was only going to ferment and dry really, really small lots of salamis. It just wouldn't be economically feasible under U.S. inspection.

We, in the future, are going to make some salamis. We want to get our hams down first. And I personally believe that there's some support as long as you are willing to dry long enough to even a low temperature fermentations and low temperature aging. But you just have to have a really, really long, dry periods.

DR. CURTIS: We have no other ideas for 1 or 2. we might go back to the top and look up with the information that we have and see if we have any -- let everybody take a look at the notes that we've taken from this and see if you have any corrections or any other comments to add to each one. That'll get you all the way back up to the top.

Looking at what we see here, does anyone have any other -- I'll give you a few minutes to

take a look at it and read it and see if you have any other suggestions or questions.

MS. RICE: This is Kim Rice. The bullet, the main bullet that says small -- some starter culture companies have been willing to provide support with validated studies.

In the next bullet, I think there is a mistake. It says, "But may not be able to provide everything the smaller studies need since the studies were done." I think that should say companies. Yeah, there we -- or processors, yeah.

DR. CURTIS: Thank you, Kim. Anything else from this section? If not, let's move down a little further.

MR. GUNTHORP: This is Greg. Back to that, where it says the 5.0-log reduction is based on the risk assessment study, would USDA entertain the idea of an establishment coming up with the supply chain that they could document and had lower than a 5.0-log risk for salmonella?

MS. SILVERMAN: Yes, I mean, so far, the main alternative, lethality, we call it, is a raw batter testing option where each lot of raw batter is combined with the two-log reduction. But establishments have the ability to support --

alternative lethalities.

And definitely, we want feedback from the committee on Number C or Letter C. That was one of the questions for the committee to consider -- should we, should FSIS accept other alternative lethalities.

MR. GUNTHORP: Because I mean, what was going through my head was I was just thinking, you know, if you had, in pork, if you had a validated intervention and then you had data, such as data loggers to demonstrate temperature control through the whole process, could an establishment support that 5.0-log wasn't necessarily required?

Because in my mind, that 5.0-log is either -- requires out-of-process control slaughter or temperature abuse in the supply chain.

MS. RENDON: Meryl, this is Tina.

MR. GUNTHORP: And then the other --

MS. RENDON: Sorry, just a quick follow-up question. You've mentioned the alternative of the batter testing. Would that be -- is the intent to describe that more, explaining that process in the guideline, or is there a reference to that information as far as exactly what that entails?

MS. SILVERMAN: Yes. So, there is a

document that's available and the link was in one of my slides from this blue ribbon task force where they do have very detailed description about that raw batter testing option.

What we do intend to do in this guideline would be to describe variations on that, like for whole muscle products, how that kind of concept could be applied, and then also how the concept could be applied to pork and poultry products since it's focused on beef and E. coli 15787.

DR. CURTIS: And Mr. Gunthorp, would you mind, so we could capture for the notes, just restating your previous comment?

MR. GUNTHORP: Sure, I made the comment about what I think about the different log reduction for lethality, that if the -- in the HACCP plan and through their process that they could support the slaughter process not being out of control and then exceptional temperature control, such as data loggers or something for the supply chain as a means to -- as another hurdle to demonstrate that they, you know, could control salmonella, for example, to levels that wouldn't require 5.0-log reductions.

MR. GREMILLION: Hi, this is Thomas Gremillion, CFA. And I'm assuming that would entail

something more than the current requirements for hog slaughter where there's not really a salmonella performance standard being verified against it.

And I'm not sure, you know, what that might look like. But maybe you have something in mind, Greg.

MR. GUNTHORP: You know, I more like the validated intervention requirement in beef slaughter, you know, because there's not -- while most plants do, there's not really a validated intervention requirement in pork slaughter.

You know, and then if you validated the slaughter and the chilling and then the temperature control after words -- and I'm not advocating for a lower than 5.0-log reduction process.

I'm just saying that it's would be another step in a food safety program to, you know, if the -- if you were close on a 5.0-log reduction and then you could also support the your slaughter in your supply chain, was keeping salmonella at the very minimum, the product is less risky than somebody that has the same log reduction and can't support that their slaughter on their pork has validated intervention and that their supply chain wasn't going above 44.7.

I mean, we all know they're not supposed to. But there's not really any HACCP controls in that. It's just temperature receiving. USDA doesn't really police, the shipment of product around the country.

MR. GREMILLION: Okay, that sounds -- I mean, maybe the transport would be the focus of salmonella.

MR. GUNTHORP: And the correct -- correct me if I'm wrong. I'm assuming that that's partially how -- and Meryl probably can speak to that -- I'm assuming that that's how USDA comes up with that risk assessment of why there's a need for 5.0-log reduction in these kind of products.

DR. CURTIS: Any other suggestions for this section or shall we go down further? Move down?

MS. RENDON: This is Tina Rendon.

MR. GUNTHORP: Could I suggest --

MS. RENDON: I just wanted to bring up on that part about the recommendation over to evaluate establishment support for these establishments before making enforcement decisions, that bullet point.

I think it would be important to point out that USDA, the district office, the EIOs, do

outreach with functions. It may be beyond their scope of knowledge, but that is an option that's available to establishments. And so, it'd probably be go to make sure to remind them that that is available.

MR. GUNTHORP: This is Greg Gunthorp again. On that bottom of that page, is it possible that we had something in there that USDA considers in a very low volume production, what they would allow for commingling of samples so that very small producers could still be testing the same amount of product but do it with less tests?

And the reason I asked for them to consider putting it in the guidance document is that that would kind of give the very small processors a safe harbor and that would provide their support to their frequency frequencies are really difficult, at times, for little processors to always support for something that USDA will go along with.

MS. SILVERMAN: Does that capture what you're looking for there?

MR. GUNTHORP: Yes. Thank you.

DR. CURTIS: Any other changes or additional comments for this section?

MS. RICE: So, this is Kim Rice. The first

bullet on A, did we say that, taking this option provides an advantage for larger establishments?

DR. EBERLY: Yeah, I said that.

MS. RICE: Okay.

DR. EBERLY: I don't know if everybody agrees, but, yeah, that is definitely what I said.

MS. RICE: Because data gaps are data gaps. And they affect everybody. This is Kim Rice again. And I just -- I'm not sure that A is the current standard for validation.

And so, I'm not sure that there's an actual advantage for larger establishments. They may be able to make a better argument, may being the key there, is not necessarily so.

DR. EBERLY: Well, my opinion was just based on the fact that large organizations would have more money potentially to just pay $50,000 for a challenge study because the lots that they're going to be making would potentially offset the cost of that challenge study.

Whereas a smaller establishment that maybe is only going to produce, you know, a thousand salamis a year, they're not going to be able to recoup the cost of that challenge study as readily as a larger scale establishment. That's what I

meant.

MR. GUNTHORP: Yeah, I agree entirely with the statement in there, because if you're a large enough establishment, you have the money to do enough testing. You can do an in-plant validation study.

DR. CURTIS: I actually looked because you're not going to be able to do in-plant if they have to do a challenge study because it'll have to be done outside of the plant.

MR. GUNTHORP: Oh, yeah. But I mean, you'd have the money to do some kind of validation of your own process, rather than being able to use a peer reviewed study that's available.

MS. REGONLINSKI: So, this is April. I just wanted to let you know, Carrie so far has been capturing, trying to capture your thoughts and kind of notes to remind you over the course of these discussions what you've talked about.

But at some point, you're going to have to try to turn them into recommendations. So just let Carrie know when you want to do that. And she can make edits to the documents to reflect your recommendations rather than just notes.

DR. CURTIS: How much more do we have at

the bottom of this? Any other -- I just want to make sure that everybody agrees on these notes so we can go back.

Everybody -- okay, let's finish up 1. So, is there anything else, any other changes you want to make on Question 1?

Okay, let's go ahead and move down to Question 2.

DR. KNIPE: This is Lynn Knipe again. And unless somebody brought this up while I -- when I hung up by accident, Kathy Glass has mentioned in the chat box that the Foundation for Meat and Poultry Research has a database of articles that could be used for validation.

And so, I'm embarrassed to say I don't know, but I'm assuming the Foundation for Meat and Poultry Research is at the University of Wisconsin. But I made a note for myself and I got to thinking, I don't believe anybody has brought that up or has discussed it. So, we should probably add that to our list of resources.

MS. RICE: So, Lynn, this is Kim Rice. I didn't say that database in particular, but that was the basis for -- it's in here somewhere, I thought -- of getting together the people who do the

research in these areas to help put together the guidance document or review the guidance document.

DR. KNIPE: Sure. Okay.

MS. RICE: So, Ohio State, Wisconsin, et cetera. I was -- I didn't -- couldn't remember what they called it either, so that's why I just said Wisconsin and Cornell and et cetera.

MR. GUNTHORP: You know, the -- Greg, again. One problem that little processors have that I don't think most academics would ever consider is that there's an awful lot of studies out there without us paying for them. We don't even have access to them.

And I've been fortunate in that I've got a university person and a USDA person that was a former EIO that both of them will at least look at studies and send them over to me, too, so that we can evaluate. But we'd spend a fortune just looking at studies that most likely wouldn't even be relevant to what we wanted.

DR. KNIPE: Yeah, this is Lynn Knipe. But you make connections too with somebody at Purdue or whatever. And I tried to make this available to our processors that because -- to our library. We have access to most of that at no cost.

So, I don't really I want to open this up, but I would provide it to everybody, but I'm usually pretty helpful if people are looking for publication.

DR. CURTIS: I would say most of the extensions or connection in each state would be that work in that area.

DR. DE MELLO: Yeah, I agree, though, most of the time I'm going to go after -- this is Amilton De Mello, Nevada. You go after your extension personnel and the rest of your state, they might be able to provide you whatever you want. So that's part of extension work, right? So, creating network connections with university personnel who work on the extension will be very useful for any type of producer.

MS. RICE: So, this is Kim Rice. Along those lines, back in the late 90s, when we were implementing HACCP, there was a network of state HACCP coordinators, most of which were your extension folks. Is that still in place?

DR. CURTIS: That's still listed on that FSIS website for the HACCP, all, very small producers. But, yes, there's still a HACCP coordinator in each state. it better each day.

MS. RICE: So, it would be good to engage them as well in some of this and utilize them.

DR. KNIPE: One thing I would comment on that, I'm not sure how up to date the list is. We used to have a conference call once a month and all of a sudden they just stopped. And I never really knew for sure what would happen, but --

DR. CURTIS: Henry -- retired.

DR. KNIPE: Oh. Well, I know there's somebody that, within our State Department of Agriculture, that was on that list along with me, and this guy's been gone for at least two years, and I think his name is still in there. So that might be the thing you might find with extension people in other states. The list may be a little bit out of date.

DR. CURTIS: Maybe the recommendation is that we update that list then.

DR. KNIPE: But yeah, I think -- yeah, that'd be good.

DR. DE MELLO: This is Amilton. I agree with that very much.

DR. CURTIS: Any other suggestion? Is there more get or more notes to log in? Okay. Any changes to in this portion?

Hearing none, let's move down to the very last part of this.

MS. REGONLINSKI: All right, just for the note takers, where it says potentially AAMP Oregon extension niche group, I think it's Niche Meat Processors -- I'm trying to give you the exact one.

It's not Oregon. They're out of Oregon. But it's Niche Meat Processors such as -- Greg, do you remember what the last two letters are of this AAMP? It's Meat --

MR. GUNTHORP: It's Niche Meat Processors Assistance Network. And they are actually based out of Oregon State, but yeah, they're -- but they help processors all around the country. I think AAMP is -- in Pennsylvania, is a Trade Association.

MS. REGONLINSKI: I would also suggest you add the universities to that because Wisconsin's group. Dr. Knipe's group's pretty extensive. Cornell has a series of workshops and classes they do. That may be more for state inspection, but it looks like it's open to everybody.

DR. CURTIS: Okay, any other changes to the notice there? If not, let's start with Question 2 and come up with actual recommendations based on these notes that we have for the -- to back to the

committee.

What are our recommendations? So, the question is, how can FSIS's industry in gathering scientific support and facilitate filling research gaps even though it's not a research funding organization? So, we had a lot of ideas. Taking these ideas, what are the specific recommendations you want to put forward?

DR. KNIPE: I might just throw out of the place to start, maybe establish a working group to look at the data that's already available and to identify gaps in the research.

DR. EBERLY: Well, but hasn't FSIS already identified the gaps? What would the working group be working to figure out how to address the gaps? Or am I wrong?

DR. KNIPE: I guess Meryl did say that she could send us a list of the gaps.

DR. CURTIS: So, let's define a little bit about the working group. Is the working group like the scientists that do research on this area, like we talked about in the notes? Or is this different makeup of people for the working group, just so we have a little bit of a definition of who the working work would be.

MS. RICE: Is there a way to put my intent, whenever I proposed that, was essentially the scientists working on that. Yes, may have to have a coordinator to kind of run that, knowing what the gaps are and then working the scientists and universities and such as that in order to organize it and be able to fill in those gaps and possibly reach out to those extension groups and trade organizations or whatever, that could possibly fund any research that is needed. That was kind of the intent whenever I mentioned that.

DR. KNIPE: And maybe instead of saying identify gaps, I think the other comment -- I can't see it on the screen, but was to establish the critical parameters or that you need to establish for companies to follow. Does that sound right?

MS. RICE: How about if we say gaps and establish critical parameters?

DR. KNIPE: That's good.

MS. REGONLINSKI: That sounds good.

MS. RICE: And the critical parameters -- this, sorry, this is Kim Rice. Critical parameters are those related to the product, not necessarily the process. Because --

DR. KNIPE: I was thinking of both.

MS. RICE: Right.

DR. CURTIS: Okay. So those researchers that did the research on all of those things to begin with, are going to work with were the clinical parameters that they had to meet.

Okay, any objections to this recommendation? Other recommendations? We have looked --

MS. REGONLINSKI: I was just going to say what about free publication of these FSIS-approved journal articles? I know we're, first of all, waiting for the guidance to come out. But in the meantime, knowing what journal articles are considered okay would be helpful, I think.

I guess I would finish that sentence with -- oh, yes, I'm sorry. I'll give it some time. Sorry. Sorry. I guess I would want it to say acceptable instead of available, just because there's lots of journal articles that are available, but it isn't until FSIS is the one decides the ones that are and are not acceptable. Thank you.

MS. RICE: But I -- this is Kim Rice. Again, acceptable is going to be dependent on your specific process, so what may be acceptable for you may not be acceptable for me. That's been my

experience. Yeah, so --

MS. REGONLINSKI: So, how about peer reviewed journals that may be accepted for support? I don't know. I know what you're trying to say. It's just --

MS. RICE: Yeah.

MS. REGONLINSKI: I just know that those articles that, you know, at the end of guidance, were like, no, not this one. Not this one. So I was trying to, you know, while we're waiting for this guidance, have a little --

MS. RICE: Right.

DR. CURTIS: So, many potential journal articles that could provide support for these products could potentially provide support and it's going to -- I agree with Kim. They're going to vary from location to location and the product to product. But you're going to have some that are going to be dismissed because they didn't like science of it or something else that they did.

DR. KNIPE: Well, another other option that Jeff Moore used a few years ago was he made a list in one of the -- I forget which one of the guidance documents it was. Maybe Appendix A. But he made a list of the unacceptable publications, the need for

a shorter list. But that's just to -- I'd just throw this out, another item on the --

MS. RICE: That's the one where Wikipedia was listed.

MS. RENDON: This is Tina Rendon. My understanding is that Meryl and them already have this list of documents, so not sure what they called it, but I don't think we need to waste our time on deciding on what to call it, but just a thought.

DR. CURTIS: Maybe we could call it the articles that will come out in the guidance document. I mean, if that's what they're using them for, if we were using the same articles they were using for the guidance document.

MS. RENDON: Good point.

DR. DE MELLO: Yeah, this is Amilton. Isn't that what this -- there is a list of articles that is listed in Appendix A already there. The best of my knowledge, I don't think you have any other data bank that actually provides it to anybody else. But there is some articles there, actually, mentioned in the Appendix.

MS. RICE: This is for the guidance document that hasn't come out on these products specifically. This is Kim Rice, by the way.

DR. CURTIS: Right, she says they already have -- yeah.

MS. RENDON: This is Tina Rendon again. I think Kim said it earlier, as far as getting as much of that information out preliminarily would be beneficial. I know I -- thinking from when they released to revise Appendix A, it kind of threw everything into a tizzy because it was recognized that there were scientific gaps and such as that.

But the benefit of getting that information or at least some of the information released, gives people, smaller processors, more of a, I would say, a head start on them being able to meet those guidance and kind of thinking about the science behind it and what they need to gather and such as that.

So, maybe it's not like a full blown release of the guidance documents, but just some resources maybe that are pulled up in there and helpful information.

DR. CURTIS: All right, does this wording meet with everybody's idea behind the concept of this recommendation?

MS. RICE: One other recommendation --

DR. CURTIS: I didn't --

MS. RICE: Oh, sorry. This is Kim. Do we want to say instead of in advance, do you want to say now? And I don't mean that like now. I mean, like in the very near future. But not a week before the guidance document comes out. Thank you.

DR. CURTIS: Okay, any other changes? And the other recommendation that we came out with in the notes, and I don't know if you want to include it, was the updating of that HACCP list, but we need the official name of whatever that's called.

And I've looked at -- for that list for that list for years, but I don't remember. What -- is it has HACCP coordinators list or somebody from FSIS might be able to give us the official name.

MS. SILVERMAN: Yes, this is Meryl. I'm not sure if what you're describing is this, but we have a list of the safe concept contacts and coordinators.

DR. CURTIS: And it has the regulator's name and the state and the contact, and it makes -- a lot of university HACCP people. So, now when your name's on that list, you get called by a lot of the FSIS inspectors to go help small plants in that area.

MS. RICE: This is Kim. I'm looking at it,

so state HACCP contacts and coordinators.

DR. CURTIS: Okay, thank you.

MS. RICE: You're welcome.

DR. CURTIS: Okay, any other recommendations for Question Number 2 there?

DR. EBERLY: Making this a resource -- making these gaps a resource priority when they make recommendations to --

DR. CURTIS: Could you repeat that, please?

DR. EBERLY: Sure, and I don't know if everybody agrees with it or not, but I said that recommending that research money or what's the term for the research that they want to do?

Somebody else has to wordsmith better than me, I think. But I'm trying to say recommend that research into these, whatever these gaps are, the -- but on the priority list -- somebody else can say this better. I'm sorry. I'm very tired.

DR. CURTIS: So, you're wanting to share the research priorities, FSIS research priorities. Is that why you're -- with funding agencies such as MEPA, trade organizations, things like that?

DR. EBERLY: Well, we talked about -- I asked, I think, earlier like who decides what the -- so some internal group decides what these research

priorities are going to be for the agency. We talked about earlier.

And so I was going to say recommend that filling in these gap be made one of these priorities, or at least recommended to that internal committee that it be made one of those what -- a research priority.

MR. GUNTHORP: This is Greg. I would like to see USDA list in their compliance guidance document the Niche Meat Processors Assistance Network as, in addition to the USDA small plant Help Desk as one of the resources for small and very small processors.

I think that's appropriate, considering that it's an extension program. And lots of times, you know, they have great contacts with these state coordinators or whatever, even if the list is updated so that they can put them in touch with somebody in their area as well as provide resources from all around the country.

DR. CURTIS: Any other recommendations?

DR. EBERLY: On the last bullet point, recommend research in trying fill in the gaps, I'd put priority, I would say, of the agency.

DR. CURTIS: Okay. Anything else? Anybody

have any objections to any of these recommendations? Moving on --

DR. EBERLY: I don't have an objection. I have a question, though. I know that the guidance is held up by the lack of information. But at some point, it would -- should the agency come out with something, even if it's not perfect, we just set an end date for guidance to come out at some time?

MS. SILVERMAN: Make a draft?

DR. EBERLY: Or a draft, you know, in the next couple years someday, maybe?

DR. CURTIS: I guess the question to prove that -- is working with -- maybe Meryl could answer this. What is that we need to get the guidance out? Is it just the gap information, so after the working group met and determined that, then could we move forward with the guidance? Or is there other things that's missing from the guidance to be able to move forward?

MS. SILVERMAN: I think you could make the recommendation related to that.

DR. CURTIS: Making a recommendation that once the working group has -- then the guidance?

MS. SILVERMAN: Yeah, I think you can make a recommendation. You know, whatever you would

recommend in terms of meeting or not.

MR. GREMILLION: All right, I had a comment.

MS. SILVERMAN: They're in development, that's what I can say.

MR. GREMILLION: All right, this is Tom. Excuse me. Somebody had a similar question. What is keeping -- again, this is maybe this is the same.

But, yeah, I'm a little unclear on what -- why the guidance hasn't gone out yet or if that's kind of defined.

DR. CURTIS: If it's only waiting for the gap information because we included the recommendation for making the guidance publication a high priority at the conclusion of the working group effort or whatever we want to call it. I think inclusion of working group -- what would we call that?

DR. EBERLY: Activities?

DR. CURTIS: Activities, yeah. So, it's getting late in the day.

DR. KNIPE: That makes sense. I mean, it seems like having the guidance would be a big help.

DR. CURTIS: And we're at the recommendation, we're making it a high priority,

which hopefully that means that it would go out as soon as possible if it's a high priority.

Okay, do we have to put things in any order, these recommendations? Otherwise, prepublication would go before the establishing of the working group or before the guidance publication because that, one, it would have to go out as soon as possible. I don't if these have to be in any order or not.

MS. RICE: I mean, it makes sense to put it in order that it's going to happen if you're just going to -- just for the people reading it, I suppose.

MS. REGONLINSKI: So I assume with the updating of the list could happen along with the working group. And what was the last one?

Oh, okay, and then we can include the last one with a Niche Meat Processor Assistance Network and I'll put that publication of the guidance as a part of that.

DR. EBERLY: I would think the pre-publishing of these journal articles could happen tomorrow. Maybe put that at the top? We already know what those are.

DR. CURTIS: Any other changes? Or do

these look okay to everybody?

DR. EBERLY: Did we decide who's in the working groups for the sake of FSIS?

DR. CURTIS: Probably couldn't since these two were kind of the ideas, scientists working in the area or other people -- you may have other people you want to include. But there's different kinds of people that have a lot of experience in this area.

Other thoughts on working or people? Hearing none, I guess we can close the parentheses on that. Any other changes before we move to Question 1 recommendations?

Hearing none, let's go back up to Question 1 and open the floor for recommendations to address what actions should FSIS take when it determines that establishment lacks the support for the lethality treatment of a fermented salt-cured or dried product? Or what are our recommendations for that?

We had the choice of the ones that were provided of the challenge. And -- or we could come up our own. Could you show up again, what was provided in the challenge, what the ABC recommendations were?

A was to take a course of an action and require adequate scientific support for 9 CFR 417.5(a)(1) and 9 CFR 417.4 (a)(1)(4) to allow -- B was to allow establishments to test and hold acceptably.

And C -- go down a little bit -- allow establishments to combine multiple scientific support documents, e.g., journal, articles or use scientific support that demonstrates 5.0-log reduction may be, in combination with increased FSIS testing; D, use regulatory discretion and allow establishments pretty scientific support or, E, a combination of the above.

What are your choices? Do you want to take one of those, or do you want to come up with different recommendations?

DR. EBERLY: This is Dr. Eberly. What about taking options test and hold and the option of, kind of cobble together multiple scientific documents with approval of, say, when an extra FSIS testing until issuance of the guidance? Would that be an option? Does anybody like that, hate that?

DR. KNIPE: Yeah, I mean, having this comment to -- I mean, having seen how long some of these regulatory documents take to come out, I would

-- my concern there would be just that this would be -- that would turn into kind of a permanent solution, you know with the guidance document kind of put off forever.

I do think the document, for increased FSIS testing kind of offsets a different -- I think that is worth exploring. But, yeah, I think making it contingent on the FSIS getting a guidance doc out could open up a can of worms.

DR. EBERLY: I guess my thought process was, and maybe I'm wrong, but if -- weren't they tasked to do this for everything that gets submitted to them, that the guidance might be faster because they're tired of doing it. I don't know. Putting it on that may push the guidance to come out, but I see what you're trying to say as well.

DR. CURTIS: But in some ways, we could interpret that regardless what recommendation we come out with, because it is, in fact, going to be until the guidance document comes out.

DR. KNIPE: Sure.

DR. CURTIS: So, they're asking us for some kind of recommendation. So, we can take, and this is a combination of -- what was that -- B and --

DR. EBERLY: C, I think.

DR. CURTIS: B and C? So, it's a combination of B and C until -- and then was the -- didn't you add an and, additional FSIS testing?

DR. EBERLY: Oh, that's the second part of C. C says, letting them combine multiple scientific support. And then it says maybe in combination with increased FSIS testing, which I feel is appropriate since you kind of Gerry-rigging this thing.

DR. KNIPE: Yeah, that was my point.

MS. RICE: This is Kim. And this question is for the FSIS folk. Is the allowing establishments to combine multiple scientific support documents, is that not currently allowed?

MS. SILVERMAN: Yes, this is Meryl. I guess it could be -- it could have been explained better. And it was more the idea that I think has been discussed before where it may be multiple documents and then of them set the premises. So, it's really using them together.

MS. RICE: Okay, so it's really using -- so, it's using documents that aren't apples to apples, but there's enough there as long as they're doing other things to ensure the safety of the product?

DR. CURTIS: Or do you want to tie the

document to our recommendation of the prepublication of articles?

MS. RICE: This is Kim again. I'm just -- if a facility is doing C already and the have put together the arguments that validate their program, but you're saying they haven't -- it really was then that they haven't made the argument for their program. Is that correct?

MS. SILVERMAN: That's how we are thinking. We were just trying to provide examples for the committee to consider, but, yeah, what we were thinking is something that's multiple article, but then meet the validation requirements.

DR. CURTIS: Oh, well, great, there's a lot of articles out there that does what it needs, that's the best possible combination. But it doesn't actually do it, hence the reason for combining it, I guess, it would be my interpretation.

DR. EBERLY: I think, as Greg pointed out, it is important that we go with this, that there'll be one authority that decides this so you don't have, you know, A, you don't have consistency and, B, so you don't have somebody like me who kind of understands this trying to decide if this is okay or

not.

So, somebody high up, you know, I keep saying WIMS (ph.). I don't if WIMS is the right group, but one particular authority that would be responsible for evaluating these kind of Frankenstein journal plans.

MS. RICE: So, is that -- this is Kim again, this is -- it's always been my experience of whenever there's a question about the validation and the way the validation's been put together, regardless of where it starts, it always ends up with Bill Shaw's group.

So, it's been my experience that it does eventually end up in what I would consider the right place for the final decision. It may take a while to get there, but it does eventually get there.

So, I think ultimately for me -- again, this is Kim, is that everybody's got to be compliant. But there are lots of different ways to get there, including the use of multi-hurdle, multi-journal articles with and without testing.

And it's the afternoon and I am not -- with the caveat that it's the afternoon and I am not at my desk in the afternoon either.

MR. GUNTHORP: This is Greg.

DR. CURTIS: So, Kim, are you saying that -- I was going to say, were you saying that the tests -- that you didn't want to insist that you had to do testing, that testing may be required, but it may not be required? Is that what -- or am I missing what -- your point you were making.

MS. RICE: I think that that is the point I was making. It depends on the situation and whether casting would or would not be required.

It gets back to this issue if I've got multiple hurdles in my process and I can utilize or I've been able to utilize multiple journal articles with multiple hurdles and string together the 5.0-log reduction and I'm validating that I'm meeting the parameters that are necessary to get me there, so I've got science pieces that may not be clean, right?

It's not the perfect line, might look a little bit like a spider chart, but it gets me to that point. And then I've got the in-plant data that shows that I can meet those parameters regularly. I may not need testing.

Or I got a spider chart, but it's not a complete. And I need to do some testing. So I'm doing that taxing just to back it up, to backfill

it.

DR. EBERLY: I read that as to -- not that the establishment would be doing extra testing but that FSIS would do extra testing because it was -- so that wouldn't be an expense to the processor. It would be an expense to FSIS. That's what I was interpreting the extra testing.

MS. RICE: Yeah, and I could see it going either way.

DR. EBERLY: And I agree.

MR. GUNTHORP: I read this one as --

DR. EBERLY: That's what I was going to say.

MR. GUNTHORP: I read this one as an alternative for establishments that never got to the 5.0-log reduction. I guess I was under the impression that if you got to a 5.0-log reduction and you could support it, validate it, that wasn't the establishment's or the processor's problems?

MS. REGONLINSKI: According to this question, it's when FSIS determines that the scientific support is missing. So that leaves it up --

MR. GUNTHORP: But that this -- this, right here, says, less than 5.0-log reduction, right? And

if we can string together a group of validated hurdles that get us the 5.0-log reduction, then we're not talking about whether or not we have support because we have support, right.

This is saying less than 5.0-log reduction, but USDA's expectation is for the reduction of salmonella in a dry-cured product. DR. EBERLY: Any consideration of reducing it from 5.0-log or two-log or whatever by using a multi-hurdle approach? Maybe that should go under Question 2 as how they -- how can they assist industry. And the suggestion, B, that the guidance an alternative of a multi-hurdle approach.

MS. RICE: This is Kim. For the FSIS folks, is that letter C less than five total or less than five individual?

MS. SILVERMAN: Yes, this is Meryl. The intention was five total, so the 5.0-log includes the concept that that comes from multiple steps that are added together.

MS. REGONLINSKI: Hello? So this -- is this how we agree on this? Or is there changes to the wording? Or do we have another recommendation? Or a different recommendation?

DR. EBERLY: I think it could use some

wordsmithing, but I'm too tired to do it.

MS. RENDON: This is Tina Rendon. You had moved the rest of the bullets to another document. Is it possible to see them side-by-side?

MS. REGONLINSKI: Yes, certainly.

MS. RENDON: Thank you.

MS. REGONLINSKI: Anything else that's suggested for rewording or changing? Or is everybody just maxed out on recommendations for this?

MS. RICE: This is Kim. Was that at the top of the document? That's the whole bullet or whole answer to -- now there's something else. Okay.

Do we need -- again, Kim. Do we need to -- state upfront that we agree that every facility should have a validated HACCP plan 417.5(a)(1) and 417.4(a)(1)?

MS. REGONLINSKI: Okay, so that'd be separate recommendations.

DR. DE MELLO: This is Amilton. This is a requirement already, right?

MS. RICE: Yeah, but I think we should --

MS. REGONLINSKI: Make our assumption clear.

MS. RICE: Yeah.

DR. DE MELLO: You're going to suggest that something is required? Because you're --

MS. RICE: Well, I think we're going -- I guess my --

MS. REGONLINSKI: The way we understand, it's required that every establishment -- okay.

MS. RICE: Right. Yeah, we reaffirm that that the recommendation is based on everybody's got to have a plan so that we're not viewed or people don't think we're suggesting that we just run amuck. And that's a technical term.

DR. EBERLY: I guess I like, but we agree that every establishment should have validated HACCP plan as to a -- and then I guess I thought it would be nice, but, comma, but understand --

MS. RICE: Right.

DR. EBERLY: -- that the agency validated HACCP plan requires validated journal, scientific support, something like that, but which is not a available at this time. Something like that.

MS. RICE: Right.

MS. REGONLINSKI: I'm sorry, could you say that again?

DR. EBERLY: Oh, goodness, I don't know.

Let's see, we agree that our --

DR. DE MELLO: Yeah, go ahead. I agree with you. I agree that justification needs to exist there because it's just a requirement. It should not be there, so the requirement that it's our recommendation. But if you want to add that, you should have a justification as to why.

MS. RICE: So because --

MS. RENDON: This is Tina Rendon. Maybe time to, you know, properly validate the program. Everyone should have a validated HACCP program but may need additional time and resources to complete this.

DR. EBERLY: Which is not currently available at. Again, this is what my point is.

MS. REGONLINSKI: So, that imply that if resources aren't available, then you don't have to validate your HACCP plan, which would pre-validate our next recommendation?

DR. EBERLY: I think we could do -- what if we said we agree that each establishment should have a validated HACCP plan for whatever. But establishments cannot have a validated HACCP plan if they do not have validated documents to build their HACCP plan -- period?

And then that leads us to the next statement which is basically the stop gap, right, until there are validated documents, guidance, right, that they can use?

MS. RENDON: This is Tina again. I'm a little concerned that that statement that some may think, oh, well, this is documentation doesn't exist. I don't have to validate my HACCP plan.

I think that you need to understand that if they don't have scientific support, they may need to actively generate it or fund it or something. So, I want to make sure we're not sending mixed signals there.

MS. REGONLINSKI: Maybe we just add this and don't make it a separate recommendation, therefore, in the meantime, we'll allow establishments to continue by combining blah, blah, blah, blah into the rest of our recommendations. That's all one recommendation, not just sort of a lead-in for it.

MS. RENDON: But if they're not available, but you have to take the second-best option that -- you have to something. Otherwise, it's like you never have to validate it.

DR. DE MELLO: But do you all agree that

that that statement of HACCP should be there?

MS. REGONLINSKI: I'm sorry, what was your comment?

DR. DE MELLO: Do you all agree that this statement on the HACCP should be there? I'm concerned it comes back to the requirement thing. I'm not sure if this is going to create more confusion or it's just an additional recommendation, if -- needs to write a requirement. That's my point.

MS. RICE: Well, it was it was option A in the question they posed to us, so it's --

MS. RENDON: This is Tina. Maybe we don't say that we agree that they should have it, just say that these, in these recommendations, this is how we're recommending that you achieve this if you don't currently have it.

MS. REGONLINSKI: But it is -- you are required to have it. So, we're just we're not disagreeing that that needs to be a part of the HACCP plan. We're just support this. There is a requirement for that currently. But it is difficult to meet, and since you can't really meet it currently this is your option. Is that not what we're saying?

MS. RICE: That's the -- what I -- this is

Kim. That's what I think we're saying.

MR. GUNTHORP: Yeah, because, I mean, if we look at it right, this is Greg, if we look at it right now, you know, there are some products being produced in the United States that don't have validated 5.0-log reductions and instead are being done with batter testing with two-log reductions.

They're being done under multiple hurdles. And USDA is allowing that, easier in some districts than others. So, I think they're really looking for us to say, should they allow those? Should they not allow those? You know, so maybe this statement is confusing.

Because, I mean, we for sure need validated HACCP plans, but I think the -- what they're asking for is, what are they going to allow for validated HACCP plans?

DR. KNIPE: This is Lynn. Would it help any at all to -- must instead of should? Or does that --

MS. RENDON: I would agree. This is Tina.

MS. RICE: This is Kim. One, two, three, four -- fifth line: available multiple, it should just be available scientific support documents. Multiple is redundant.

DR. EBERLY: I wrote something in the chart because I just couldn't -- I don't know. Would this work better? I didn't type the numbers.

Last year, whatever and whatever the -- is HACCP plan. The prior HACCP plans cannot be created without validated scientific support documents. Therefore, we recommend whatever recommendations.

Would that be something -- acknowledge the fact that they knew about it, HACCP plans, but also acknowledged that it's impossible to do so if there's no scientific support for a HACCP plan for these particular products?

MS. RICE: Are we meeting again in the morning as a subcommittee or are we going directly in?

MS. REGONLINSKI: So, this is April. Subcommittee 2 needed more time for tomorrow. So, you can also have more time for tomorrow, if you would like to review that. I think it's another hour, hour and 45 minutes before you would have presented to the committee.

MS. RICE: I think another 15 minutes would be great at this point.

MS. REGONLINSKI: Well, I think Subcommittee 2 is going to take more time. So --

DR. EBERLY: Or even just 15 minutes tomorrow after we have dinner. Not as physicians, not in other work.

DR. CURTIS: Okay, we plan -- this is it for today, and we plan to meet tomorrow to review our recommendations, give everybody a chance to think about it overnight. And if there's any changes they want to make, we'll make them in the morning?

MS. RICE: Yeah. Is there any way we could get this so that we can at least kind of look at it maybe with our first cup of coffee before we get on the call?

DR. SNIPE: Is it possible to get the comments that were in red? Because I was trying to read those and as the afternoon went on, the red was just kind of blurring together. Is it possible to get that and look at that tonight?

So, I actually think there was another point I was interested in in the first one, but -- because I didn't have control of where -- what I was looking at, I had trouble finding it. Can we get a copy of that tonight?

DR. CURTIS: Is that possible Carrie or April? Can you tell us?

MS. RICE: They may be conferring.

MS. REGONLINSKI: This is April. I think that's fine. Carrie has them saved and can email them, but we just don't -- we ask that you do not share them with anyone outside the committee. And do not deliberate outside of this forum, please.

DR. CURTIS: Okay, is that satisfactory with everybody?

DR. KNIPE: That's be great?

DR. CURTIS: Yes. Okay, we'll get them emailed to us and then we'll look at them tonight and make any changes first thing in the morning.

April were you taking requests or do I need to email Valerie and let her know?

MS. REGONLINSKI: I can request Valerie -- from that, from Valerie. This is April.

DR. CURTIS: Okay.

MS. REGONLINSKI: Also, there is going to be a wrap up at the end of the day. So, we ask that you stay on the line.

DR. CURTIS: So, we just take a break between now and 4:45?

MS. REGONLINSKI: Yes. I think it's -- I've seen 4:30 and I've also seen 4:45.

DR. CURTIS: Well, she told us it was

changed to 4:45 because we didn't have any public, but if --

MS. GREEN: This is Val again. Sorry about that. It looks like Subcommittee 2 is wrapping up and they will be joining us shortly. So please take a break and we will reconvene at -- I would just give them some time and give you all a break. We can reconvene at 4:45. Is that okay? Or would you like to reconvene sooner? I think they'll be dialing in shortly. Is that fine?

DR. KNIPE: 4:30 would be good.

MS. GREEN: Take a two-minute break? That's fine. We'll see. How about 4:35, and hopefully we'll have everyone back on the line at 4:35.

DR. CURTIS: Okay, thank you, Valerie. Sounds good.

(Off the record.)

(On the record.)

AT&T EVENT PRODUCER: Welcome, and thank you for joining today's conference, National Advisory Committee on Meat and Poultry Inspection Public Meeting.

My name is Will Dubois (ph.), and I am your event producer for this conference. Just as a

reminder, please ensure you have opened the chat panel by using the associated icons located at the bottom of the screen.

And if you require technical assistance, please reach out to the event producer. All audio lines have been muted at this time. To submit a written question, you can select all panelists from the dropdown menu in the chat panel, enter your question in the message box provided and then send.

And with that, I'll turn the call over to the moderator, Val Green.

MS. GREEN: Thank you, Will. It seems like there was a very productive dialogue in both of the subcommittee sessions. And I want to thank our respective subcommittee chairs. For Subcommittee 1, Patricia Curtis and Subcommittee 2, Ms. Casey Gallimore.

And I would like to ask the subcommittee chairs at this time if they need additional time in the morning to reconvene your committee.

DR. CURTIS: Subcommittee 1, we will.

MS. GALLIMORE: Subcommittee 2 as well.

MS. GREEN: Okay, we will modify the scheduled to allow more time and we'll also ensure that each of you or to the committee members have a

copy of the draft recommendation. Do not deliberate or share your draft recommendations outside this board.

Also, I'd like to take the time to thank the subcommittee designated federal officials Rachel Edelstein and April Regonlinski. I'd like to acknowledge and thank Carrie Clark, Jonathan Huang, Scott Updike, and Shercoda Smaw for taking vigorous notes during the deliberations.

And last, but certainly not least a special thanks to Patrice Palmer, Shekelle Bazemore and Susan Ikbakli (ph.) who helped with the appointments of the new committee members and planning this meeting.

So, without further ado, next slide, please, we'll go ahead and review the agenda for tomorrow. This was the original agenda. Next slide.

So, what I'd like to do is move the committee deliberations to 9:15 in the morning. We'll start at 9:00 a.m. This committee deliberations will start at 9:15, and we will have the committee chairs report out at 11:00 a.m. Is that enough time to complete the recommendations for Subcommittee 1 and 2?

DR. CURTIS: Yes.

MS. GALLIMORE: Yes, for Subcommittee 2 -- I don't know about Subcommittee 1, but I don't I don't know about anyone, but I don't think we'll need that much time, so we could potentially do -- I think we'll get through it 30 to 45 minutes. But that depends also on how much time Subcommittee 1 needs.

DR. CURTIS: I don't think we need that much time either. And I was just saying is what Subcommittee 2 was saying.

MS. GREEN: Would you like to start at the report at 10:00 a.m.?

MS. GALLIMORE: That works for Subcommittee 2.

DR. CURTIS: It works for Subcommittee 1.

MS. GREEN: All right. Okay, so we'll start tomorrow at 9:00 a.m.. We'll move to the subcommittee deliberations at 9:15 and then we'll report out -- we'll start to report out for the subcommittees at 10:00 a.m. And each subcommittee will have 30 minutes to provide their report.

After that, we'll convene -- well, actually will still be on the same line, but -- we'll be on the same line for the subcommittee reports. And

then we will move to full committee discussions for the committee as a whole to review the recommendations and vote on a final report.

Are there any final questions or comments from the subcommittees? Or any comments from the audience? That's --

MR. HARRIS: This is Joe Harris with Southwest Meat Association. Just a quick request. If you guys could send out the information to reconnect in the morning, because we've been connected and we connected so many times, I'm not sure which link to use and which number to use. If you can send it, send that out to us again this evening, that would be great.

MS. GREEN: I'll ask the event producer. Will, would that be possible for an AT&T to send out the link for the link for the speakers again?

AT&T EVENT PRODUCER: The link for the speakers to which parties?

MS. GREEN: If I provide a list would that be good? If I can provide a list or a list of names?

AT&T EVENT PRODUCER: If you provide me a list of email addresses, I believe I could send out the address for the speaker side, yeah.

MS. GREEN: Okay, thank you. Are there any --

MS. EDELSTEIN: This is Rachel. I have a process question. Can we send our -- we are putting together the note for Subcommittee 2. Can we send our notes to them tonight or tomorrow morning before the committee starts? Is that allowed?

MS. GREEN: Yes.

MS. EDELSTEIN: Okay.

MS. GREEN: Yes, just don't -- the committee is not to deliberate this evening, only during the public forum. But they are permitted to review their notes and make comments and then once they reconvene for the deliberations, then they can continue to refine and develop the recommendations.

Any other questions or comments?

MR. WILLIAMS: Yes, Valerie, Byron Williams. Will there be a different access code and number for the subcommittees? Or will you provide that in the morning once we divide for the subcommittees after the general starts at 9:00?

MS. GREEN: I will ask the event producer to send out that information as well for the subcommittees.

MR. WILLIAMS: Okay.

MS. GREEN: So once again, when I will ask the event producer, I will provide the list of names and email addresses and ask them to send the main event line as well as the breakout sessions, the dial-in information for the breakout sessions.

AT&T EVENT PRODUCER: And this is for a conference at a later date or this current conference?

MS. GREEN: That's for tomorrow morning.

AT&T EVENT PRODUCER: Okay.

MS. GREEN: Yes. Are there any other questions or comments? All right, hearing none, we'll adjourn the meeting at 4:47 p.m. We'll start again at 9:00 a.m. in the morning. Thank you all.

(Whereupon, the proceedings in the above-entitled matter were recessed, to reconvene the next day.)

C E R T I F I C A T E

This certifies that the attached proceeding before the

UNITED STATES DEPARTMENT OF AGRICULTURE

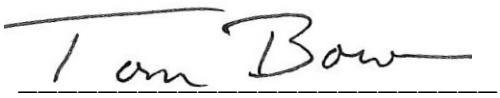
FOOD SAFETY AND INSPECTION SERVICE

IN THE MATTER OF: NACMPI Public Meeting

PLACE: Via WebEx

DATE: September 24, 2020

was held according to the record, and that this is the original, complete, true and accurate transcript which has been compared to the recording accomplished at the hearing.



R. Thomas Bowman

Court Reporter