Event Producer: Welcome and thank you for joining today's FSIS Webinar on Revised Appendix A and B Guidelines. Before we begin, please ensure you've opened the WebEx chat panel booth in the associated icon on the bottom right corner of your screen. Please note that all audio connections will be muted until the Q&A portion of the call. You are, however, welcome to submit written questions throughout the presentation, and these will be addressed during Q&A. To submit your questions in writing, select all panelists from the dropdown menu in the chat panel, enter your question in the message box provided, and send. As a reminder, this conference is being recorded. If you require technical assistance, please send a chat to the event producer. With that, I'll turn the conference over to Paul Kiecker, administrator for the US Department of Agriculture's Food Safety and Inspection Service. Please go ahead.

Paul Kiecker: All right. Thank you very much and good morning, everyone. Welcome to the webinar on Appendix A and B. We've created these webinars because small and very small establishments have asked us for more information about the changes. So we held two webinars back in May. We held one on Monday, and this is the second one of our September series. I also want to let you know that those meetings that we had earlier are all recorded and available for you on the FSIS website.

So the establishments that utilize previous versions of Appendix A and the Appendix B are expected to have the support for using those, or they can have additional support. And the effective date for that is December 14th of 2022. So you can either use the 2021 guideline, or you can have the alternative support. But don't wait until the deadline before you start looking at the program and what your support is, and if you need to make any changes or not because we understand how diverse a lot of these products are and processes that are involved. So make sure that you are reaching out early enough. We won't be able to assist everyone at the last minute. So make sure you give yourself plenty of time.

We hope that you find these webinars beneficial. We're holding these to provide you with information, allow you the opportunity to ask questions, and also to get answers to the questions that you have. If you have any questions, make sure that you ask them here. If you come up with questions later on, make sure you reach out either to the frontline supervisor or the district office, and see if have they can schedule an EIO to do an onsite visit with you or to answer questions that you have. Again, I appreciate you being here today and taking the time to address this concern. With that, I'll turn it over to Dr. Scott Updike to start with the presentations. Scott?

Scott Updike: Thank you, Paul. Today, we're going to be presenting an update on the revised version to Appendix A and B, which we issued last December in 2021. This is the agenda for today's webinar. In particular, I like for you to note that we want to answer as many of your questions as possible. So we'll have an open question session after we go over the Appendix A, the cooking guideline. We'll have another question session after we do the stabilization guideline, and then we'll

have a third question session after the scientific gaps update. As we go along with the presentation, I encourage you to go ahead and enter any questions you may have in the chat, and we'll get to them when we get to the question session.

Very briefly, we want to share the history of the guidelines, which you may be familiar with, as it helps to explain how we came to these 2021 revisions. Initially, FSIS introduced prescriptive command and control cooking and cooling regulations that define how, step by step, to cook and cool certain products such as roast beef that had been associated with outbreaks in the past. When FSIS moved to HACCP, it removed those requirements, and instead implemented performance standards that set requirements for the amount of reduction or outgrowth allowed, but didn't require particular ways to achieve those standards. FSIS only implemented performance standards for the same products associated historically with outbreaks. Along with the performance standards, FSIS issued guidelines and dependencies to the final rule called Appendix A and B. These provided optional safe harbors taken from the old command and control regulations intended to help establishments producing products under the performance standards to comply. Over time, however, the guidelines became user support for many more products than they were originally intended, which led us in 2017 to try to clarify their use.

In June 2017, FSIS issued revised versions of Appendix A and B. When the guidelines were reissued, we received a number of comments on them that led to a delay in verification. FSIS has responded to all the comments in the Federal Register that was issued in December of 2021, announcing the 2021 revised and final versions of Appendix A and B. Many comments related to common cooking and stabilization processes for which establishments have used Appendix A and B as support, even though these processes couldn't achieve the critical operational parameters included in the revised guidelines.

So this led us to the 2021 revisions that reflect updates and response to comments received on the previous version. In addition, the guidelines have been revised to include recommendations from previous versions and new updates based on up-to-date science. The 2021 guidelines represent FSIS' current thinking on topics. Establishments that utilize previous versions of Appendix A or B as support should either update to the 2021 guidelines or identify alternative support by December 14th, 2022. The time provided includes the time the establishments may need to gather new initial implant validation data, should the change in scientific support result and change the critical operational parameters being implemented. So we recommend establishments start considering the changes now.

Along with the guidelines, FSIS issued Notice 59-21 on December 14th. This notice instructed IPP to notify establishments that revisions to Appendix A and B are available, and that they have until December 14th, 2022 to begin using the 2021 guidelines, or identify alternative support. It provides instructions for EIAOs when performing Food Safety Assessments in establishments using FSIS'

appendices as scientific support. The notice also includes attachments with changes from the previous versions of Appendix A and B. And we indicated FSIS will provide further instructions before the implementation date this December. We're also doing these webinars for industry to help with it. And this webinar is being recorded and will be available for you to view at a later date.

First, we're going to talk about the cooking guideline, also called the Revised Appendix A. Before going into the specifics of the guidance, we wanted to set the stage for why we have the guideline, and it's to help establishment support their lethality treatment, specifically cooking. Lethality is defined by FSIS as a process or combination of processes that ensure specific, significant reduction in the number of Salmonella and other pathogens in the product, as well as their toxins or toxic metabolites. The most familiar lethality process is cooking, heating the product to kill hazardous bacteria. But other processes like fermentation, salt curing, and drying can be used to reduce the number of salmonella on a product.

The 2021 Cooking Guideline is really intended to support lethality from cooking and not these other processes. For these other processes, FSIS has a guideline with food safety lessons from the 2011 Lebanon bologna outbreak. This guidance can be applied to other semi-dried, fermented sausage product. We also recently updated our HACCP Validation webpage under the section HACCP Validation by Product to include journal articles and other peer-reviewed scientific information that can be used as scientific support for the lethality treatment of fermented products, salt-cured products, and dried products. In addition to the listing of support documents, FSIS included links to electronic journal articles where possible.

There are a number of biological hazards of concern during cooking. One thing we tried to do with the revision is clearly identify these. Staphylococcus aureus is a hazard present in raw products whose outgrowth during the heating come-up time with cooked products should be controlled. There are a number of other hazards present in raw products that the lethality treatment should be designed to destroy that are listed on this slide. Although all of these hazards are in concern, Salmonella is considered an indicator of lethality because the thermal destruction of Salmonella in cooked products would indicate the destruction of most other pathogens.

FSIS has defined and codified the log reduction of salmonella that must be achieved by lethality treatment to ensure specific products are safe. Products that have performance standards include roast, cooked, and corned beef; cooked uncured meat patties; and cooked poultry products. Other ready-to-eat products not under a codified performance standards still must be processed to ensure no strain of Salmonella survives on the finished ready-to-eat product. FSIS guidance is being used to ensure Salmonella log productions are achieved per product under a performance standard, as well as products that are ready to eat but do not have a performance standard.

The 2021 Cooking Guideline is designed to help establishments understand the biological hazards during cooking, meet the codified regulatory performance standard, and ensure the safe production of cooked ready-to-eat products. The guideline has options establishments can use to achieve lethality of Salmonella and other pathogens. It also has a new concept of processes that do not have validated research available referred to as scientific gaps and options establishments can use until research is available. It has resources for alternative support because no one is required to follow the Appendix A options. And it has recommendations for evaluating cooking deviations.

This slide has a summary of changes that are also included in the guideline. The goal is to help establishments understand how they are impacted by the revisions. Because remember, if an establishment used the 1999 or 2017 version of Appendix A, they will have until December 14th, 2022 to update to the new version or identify alternative support. So among the changes, the revision specifies those products that are covered by the guidance and those that are not. And we'll talk more about this briefly. It includes food safety significance of relative humidity recommendations. It specifies relative to humidity should be addressed for all cooked products unless establishments can support that it does not need to be addressed. It provides additional resources for selecting relative humidity options, even though those options has not changed. It provides more information about situations when relative humidity does not need to be addressed, including that natural casings maintain relative humidity. It includes critical operational parameters from 1999 guidance for products included in scientific gap. And again, provides more details for evaluating heating deviations.

One thing that guideline does, which I mentioned, is address products covered because this was something that was not entirely clear. Specifically, the guideline addresses lethality of pathogens in meat and poultry products by heat treatment, including for products that are cooked to lethality but classified under a not-ready-to-eat HACCP plan. Throughout the document references to meat and poultry products may be considered inclusive of meat by-products, meat food products, and poultry food products as defined in 9 CFR, unless otherwise stated. We added this in response to questions about whether the guideline can be applied to products such as liver. And yes, it can.

We wanted to be very clear on the products that are not covered as we've seen over the years that establishments were applying FSIS guidance to products it was not intended for. And that was causing a potential huge safety hazard. These products included the following, and where possible, we provide alternative support. Fish of the order Siluriformes such as catfish: FSIS Cooking Guidance was not validated for fish, but we included a link to FDA's fish guidance which has cooking recommendations that can be used. Pork rind pellets: FSIS Cooking Guidance does not apply with the cooking or rendering of pork skins into a pellet, which is a very different process than cooking something like a roots. Establishments may use the cooking requirements in 9 CFR 94.8 B4 as support for cooking pork skins into a pellet.

Rendered lard and tallow: FSIS Cooking Guidance does not apply to the rendering of animal fats such as lard and tallow, which due to the high fat content generally need to reach a higher temperature and longer dwell time to achieve the same reduction in Salmonella. However, we do indicate the cooking requirements for rendering in 9 CFR 315 1A can be used to support for the lethality steps. Also, we've gotten some questions about hot filling, and although rendered lard and tallow cannot use Appendix A to support lethality, it can still be used to support hot filling temperatures and consider a product not post-lethality exposed. Dried products processed under dry condition: FSIS Cooking Guidance does not support lethality for a process that relies on drying a lamb such as biltong, nor does this guidance support a process where the drying step comes before a cooking step that does not apply humidity or does not apply humidity during cooking at sufficient levels to rehydrate the product surface, such as biltong or country-cured ham that's cooked in an unsealed oven after drying.

This was identified in response to an outbreak where an establishment cooked country-cured ham more than once under dry conditions. In addition to dried products, FSIS Cooking Guidance also does not apply to those products that are fermented but not cooked as well as salt-cured product. I mentioned previously that FSIS has a guideline for Lebanon bologna and other semi-dried, fermented products. And that the HACCP Validation webpage under the section HACCP Validation by Product has been updated with journal articles for these products. Finally, Appendix A does not cover partially heat-treated, not-ready-to-eat product. We noticed some establishments are putting products to a partial heat treatment, such as 145 with no dwell time, and citing Appendix A even though Appendix A does not contain those parameters. So we've tried to be very clear Appendix A does not cover products that are partially heat-treated. Establishments can use the guidance and emphasize Appendix B for these products. As you'll hear Aaron talk about this, this guidance addresses both heating come up time and cooling time for partially cooked not-ready-to-eat products.

FSIS Appendix A identifies three critical operating parameters to ensure adequate lethality when cooking meat and poultry products. The first is time, the second is temperature, and the third is relative humidity. I would describe more about each of these on the following slide. The first two parameters I want to focus on are time and temperature. In particular, most people are familiar with the internal endpoint temperature and the hold time. The other aspect with time is the heating come-up time, which is the time the product is between 50 and 130 degrees Fahrenheit.

So more specifically in terms of heating come-up time. Time temperature is used to monitor come-up time to ensure Staph aureus is controlled. The 1999 version of Appendix A mentioned a potential hazard if the come-up time was longer than six hours, but didn't clearly describe it as a critical operating parameter for all products. Since the 2017 version clarified the come-up time limit, we've heard that six hours can be difficult to meet for some products, so

we have addressed that by explaining how establishments can support custom time and temperature parameters using alternative support, and also by identifying a scientific gap.

I will discuss this in more detail. But in short, the scientific gap is a common cooking or cooling process which had been using Appendix A and B as scientific support, but cannot follow the new parameters. These are products for which there is no imminent public health hazard, but there is also no other scientific support we can provide. For these processes, establishments can cite the scientific gap as support for their process. In this case, as support for not addressing heating come-up time for products such as ham and brisket that are too big to physically meet the recommendation, until new research can be conducted. At the end of this presentation, I will discuss progress FSIS and others have made on filling the scientific gaps.

In terms of internal endpoint temperature and hold time, those have not changed and are contained in a number of tables. We've tried to make it more clear that there are different tables for meat and poultry. And for poultry, there is the older poultry recommendation to cook to 160, or the newer tables for chicken and turkey that take into account fat. Again, the cooking times and temperatures have not changed. For the poultry time temperature table, if an establishment does not know that fat content of the product, FSIS recommends using the worst-case scenario of 12% fat in the table.

We've also added more detail about monitoring. This is in response to a number of recalls of undercooked products, where the establishment technically met their CCP but were sending uncooked products out the door. What that indicates is that the monitoring frequency was not sufficient to detect deviation. We've added guidance to ensure that cooking procedures should be designed to ensure all products in a bachelor lot achieved lethality. Monitoring procedures should be designed to detect the deviation when it occurs. Establishments should carefully consider the selection of the critical limit as well as the design of their monitoring procedures. And included lessons learned from several recall attributed in part to insufficient monitoring procedures.

Specific information about temperature and time. The other critical operational parameter for cooking is a relative humidity. Scientific research has shown that moisture is important to ensure lethality on the product surface during cooking. Moisture in the cooking environment does this in two ways. First, it keeps the surface hot by preventing evaporative cooling. Evaporative cooling is what keeps you cool when you sweat. Humidity in the air keeps the product hot, just like being in a humid place like a rainforest would make you feel hot. Secondly, it prevents desiccation and pathogens from developing heat resistance. Salmonella in particular is known to become more heat resistant when it is dry as part of the cooking process. Any pathogens on the interior of most meat and poultry products will stay hydrated due the internal moisture of the product. So lethality internally is likely to occur as long as the time and temperature combinations of the products are obtained. On the surface, pathogens are more

likely to become dry and become heat resistant. So surface lethality treatments may be distinct from internal lethality treatment.

We've tried here to illustrate this concept and why it's important to have moisture in the environment. When you get too hot, you produce sweat. When the sweat evaporates, it cool-

Scott Updike: ... too hot, you produce sweat. When the sweat evaporates, it cools you down. Through a process called evaporated cooling, as the sweat evaporates, it takes heat with it and cools the surface down in the process. So evaporation equals cooling.

Now consider sweating in a tropical environment where there is high humidity. You feel wet, sticky and the air is heavy. The air has too much moisture for your sweat to evaporate, so you stay hot. If you were in a desert, the dry heat would allow your sweat to evaporate, cooling down your skin. The same thing happens to meat and poultry cooked in the oven. If the heat is dry, moisture evaporates, letting the surface stay cool. So cool, bacteria may not be killed, but if there's a lot of moisture in the air, relative humidity is high, the surface of the product stays hot and bacteria are killed.

The first step to using FSIS cooking guidance is to choose a time temperature from the appropriate table. There are two tables for meat, and then two different tables for poultry. Establishments must choose a table that matches their product and the required or targeted pathogen reduction.

The next step is to pick a relative humidity option. This table clearly summarizes the FSIS Relative Humidity Options, and when they can be used. Note, all of these are consistent with the 1999 version of the guidance. We didn't make any changes to the options, just how they are presented.

Both the 1999 and 2017 guidance describes several situations which do not need to address relative humidity. These situations fall under two major groups. One, where the moisture around the product is inherently maintained like immersion cooking. The second, where the product is subject to direct heating methods that will rapidly heat the product surface, inactivating bacteria on the surface before they can dry out and become heat resistant. An example is heating on a grill over a direct flame. We've gotten a lot of questions around small mass products and when relative humidity does and does not need to be addressed. So what we've done is to better clarify that all products should address relative humidity unless they fall into one of these two. We also have a number of scientific gaps, which I will talk about, that an establishment can use to support relative humidity does not need to be addressed while research is conducted. Establishments which cook using one of these methods or situations can support that they do not need to address or monitor relative humidity as part of their procedure and hazard analysis during decision making.

If an establishment wants to apply an alternative lethality, for example, only a five log reduction in each product, then they must provide additional support. The guidelines include examples of additional support, such as source materials that have been treated through these pathogens or conducting a baseline study for Salmonella in the raw source material.

However, we have moved this information to an attachment and also removed some of the detail sampling information because a lot of establishments interpreted this as applying to all processes, including those using the traditional six and a half or seven log table when that was not the case. The key takeaway today is that you do not have to perform sampling if you want to use the standard time temperature tables, but you cannot use the five log table unless you provide additional support.

Establishments must consider any potential food safety hazard at the step in the process where the non-meat ingredient is "received" into the food safety system and document any controls that needs to support its decisions about those hazards. Establishments should have letters of guarantees, COAs, or other information to support the safety of the ingredients when it is added to a meat or poultry product after the meat or poultry product undergoes a lethality treatment. Letters of guarantee alone would not be sufficient to support the safety of the ingredients added to the product unless they indicate how each loss of ingredient is processed, tested, or otherwise treated to ensure it's safety. However, letters of guarantee would be sufficient support for the safety of pre-packaged ingredients such as ketchup or mustard that have not been associated with previous recalls or outbreak.

Mentioned before the 2017 version of this guideline was published, FSIS became aware of several types of processes, which had been using appendix A and B support, but were not supported when the agency clarified the guidance's limitations. Additionally, the agency could not identify scientific literature to support certain products and processes. FSIS encourages establishments to conduct challenged studies when appropriate. However, we realize it may not be cost effective for every establishment to conduct individual challenged studies. Therefore, we've posted research priorities on our website to communicate clear research needs with USDARS and academic researchers. FSIS is calling these specific properties in the research needs scientific gaps. To share information in a timely manner, FSIS is updating the guidance to address public comments received on the 2017 guidelines, recognizing that gaps remain in knowledge relating to certain cooking processes. While waiting for research results, FSIS is allowing establishments to continue to use the 1999 version operating parameters by including them in these scientific gaps in the 2021 guidelines.

So establishments using the older versions of appendix A and B still need to update to the newer versions. There is a vulnerability that these parameters have not been validated to achieve lethality or controls for former growth using microbial challenge studies or published research, but researchers need time to

perform such studies. These older parameters included in the gap are intended to be used as scientific support for decisions in the hazard analysis. Again, at the end of this presentation, I will discuss the progress FSIS and others have made in filling these scientific gaps.

There is a vulnerability in following the scientific gap, but I want to be clear that establishments can use these scientific gaps as support for decisions in their hazard analysis. We also wanted establishments to be aware that the processes have not been validated to address all hazards of concern. The original research used to develop these critical operating parameters were performed while only the few products covered by the performance standards to included in the '99 versions of appendix A. If a process deviation occurs for a process that's included in the scientific gap, it's unlikely an establishment would be able to identify adequate support for product safety without performing product testing.

If FSIS or the establishment collects a ready to eat sample that is positive for salmonella or the establishment is implicated in a food safety investigation related to salmonella, FSIS would verify as part of the corrective actions that the establishment can support inadequate lethality was not the root cause if it wants to continue to use the older recommendation. As additional data becomes available, FSIS will change the recommendations for processes that fall under one of these scientific gaps. We're not going to go into details on recommendations we've made for each gap to reduce the vulnerability. We want establishments to be aware these recommendations are there, but they not required.

As I mentioned earlier, relative humidity is a critical operating parameter for all cooked products, but FSIS options were originally developed for cooking large mass products like roast beef in smokehouse ovens where cooking is often several hours. So there are some processes such as short time, high temperature cooking that can't follow FSIS relative humidity options. For example, a process that cooks chicken tenders in a continuous [inaudible 00:33:30] oven may only cook for 10 minutes or less.

For short cooking, the only FSIS option is to apply 90% relative humidity, the entire cooking time. However, relative humidity is not the most accurate method to measure air moisture at high temperatures. There's some research on certain processes that use dew point, percent moisture by volume or wet bulb temperature to ensure lethality on the product surface. However, more research is needed to support alternative ways to ensure lethality on the many different products which are in this research gap.

FSIS has identified short time, high temperature cooking as a process that can continue to follow the 1999 parameters. However, continuing to follow the 1999 parameters creates some vulnerability and we're going to be clear about this. In this case, if relative humidity is not addressed, there may be insufficient log reductions of salmonella. Salmonella adulterates ready heat products, so

cooking without addressing moisture around the product could risk under processing and product adulteration. So this gap can be referenced in the hazard analysis as scientific support for why relative humidity is not addressed in this process. The establishment must still follow the other parameters of timely temperature if following this option.

Another such gap is products cooked used by microwave cooking methods that are not designed to control relative humidity. Processes that meet this gap include those in which a meat or poultry product is cooked using a continuous or non continuous microwave oven. Establishments can use this gap as support for use of any FSIS time temperature table addressing all critical operational parameters except relative humidity.

The next gap is for products cooked using cooking methods that are not designed to control relative humidity, other than microwave ovens. Processes that meet this gap include those where product is either cooked in ovens that are not designed to be sealed or not designed with a mechanism to introduce steam. So you can see a picture here of a convection oven, which is an example of a type of oven not designed to be sealed and many of which cannot introduce steam, or the other type of product is this for barbecue products cooked under dry heat to meet the labeling requirements. Again, establishments can use this gap as support for use of any FSIS time temperature table addressing all critical operational parameters except relative humidity.

Other processes that may inherently maintain relative humidity around the meat and poultry filling, but cannot follow one of the relative humidity options. Processes that meet this gap include those that involve use of an edible wrapping that fully encloses a meat or poultry product filling before cooking. Examples of these wrappings include dough, leaves and edible rice paper. For these types of product, relative humidity is not desired for browning and other quality reasons, but FSIS also has no other support to point to that these products are safe without addressing relative humidity. Again, establishments can use this gap of support for use of any FSIS time temperature table addressing all critical operational parameters, except for relative humidity.

The next gap is for processes where the drying step comes before cooking under moist conditions. Processes that meet this gap include those in which the products are dried to reduce the water activity and then cooked using one of the following options that ensures high relative humidity. So you can use option one, three or four, cook in bag or immersion cooking. Here, the concept is that by cooking the dried product one under moist conditions, the surface will be rehydrated. Although no one has tested this in the literature, which is why it is a scientific gap. Until more research is conducted, establishments can use this gap to support any FSIS time temperature guidance, addressing all critical operational parameters and using one of those listed relative humidity options.

The last gap involves products with long heating up time. This gap applies to processes such as ham and brisket that, due to their size, require a heating

come up time longer than six hours. Again, this is due to the physical size of the product. For these products, this gap can be used to support any FSIS time temperature guidance, addressing all critical operational parameters, including relative humidity, without addressing come up time as a critical operational parameter.

This table is intended to better explain the difference between scientific gaps I just went through and also the list of products I shared at the beginning that are not covered by the guidance. There are some products where research or outbreaks demonstrate FSIS guidance is insufficient to result in a safe product. These products cannot use FSIS guidance as scientific support and must identify alternative support. An example is salt-cured and dried country cured ham cooked multiple times, which was a contributing factor in an outbreak. There are other products where there is no evidence showing any imminent food safety concerns, but current parameters cannot be applied. These products can use FSIS guidance. The 2021 revisions includes the '99 parameters that can be applied. An example here would be salt-cured and dried country cured ham cooked once. FSIS guidance was not designed for this product, but no evidence showing imminent concern.

Finally, for appendix A, the guideline has information on how to handle heating deviations. FSIS has defined three common types. One, the establishment fails to meet the time temperature perimeter in the lethality CCP for meat or poultry products, two, the establishment fails to maintain sufficient humidity during the cooking steps, or three, low heating come up time occurs, which allows product to remain between 50 to 130 for more than six hours. The guideline has information on how to use pathogen modeling and sampling to determine product disposition after deviations.

So to summarize for appendix A, FSIS revised its cooking guidance in 2021 in response to public comments. FSIS guidance contained time, temperature and relative humidity recommendations for cooking meat and poultry. The guidance specifies those products that are covered by the guidance and those that are not. It also includes older parameters for some common cooking processes that can be used until further research is conducted because there's insufficient evidence showing imminent food safety concerns. As a reminder, establishments that used previous versions of appendix A or B as support need to update to the 2021 guideline or identify alternative support by December 14th, 2022.

Before we get to the questions, we also wanted to share the takeaways we shared with our inspection program personnel during their webinars in August, so that everyone is receiving the same information. Per FSIS notice 59-21, IPP are to make establishment management aware of the revised guideline. FSIS will provide further instructions to IPP before the December implementation date. These instructions are in an FSIS notice and will describe the verification procedures IPP are to follow in relation to the revised 2021 guidelines, including verification procedures for processes within a defined scientific gap. The specific

change from the previous version are listed on pages six to eight of the guideline.

We want to be sure IPP are aware that the options in the body of the 2021 guideline (time, temperature, relative humidity parameters) may be used to support by establishments producing ready to eat products to meet element one for validation. The time, temperature and relative humidity options from the previous version of the guidelines, '99 and 2017, did not change and are included in the revision. Establishments are not required to follow the parameters in appendix A and may use customized processes and alternative support.

Establishments using common cooking processes that use the '99 version of appendix A, but cannot achieve the relative humidity or heating come up time in the revised guidelines, may be able to use a scientific gap of support for not addressing the critical operational parameter. There is a vulnerability with using the scientific gap of support for not addressing the critical operational parameter, but FSIS has determined there's not an imminent public health safety concern, and the establishment can use a scientific gap as support until more research is conducted.

Although, as we mentioned earlier, it's FSIS or the establishment collects a ready to eat sample that's positive for salmonella or the establishment is implicated in a food safety investigation related to salmonella, FSIS would verify as part of the corrective actions that the establishment can support inadequate lethality was not the root cause if it wants to continue to use the order recommendation. IPP assigned establishments that produce products falling into a scientific gap are encouraged to refer questions to their supervisor, or as needed, ask questions via askFSIS to ensure they have a thorough understanding of the process products to ensure verification activities can be correctly performed, determine regulatory compliance after December 14th. Aaron will share the specific askFSIS information at the end of this presentation.

Now we have time for questions on the cooking guideline and revised appendix A before we move into the stabilization guideline. Could the event producer remind everyone how to ask questions?

Event Producer: All right. If you would like to ask your question verbally, you can select the raise hand icon in WebEx. You'll hear a beep when your line is unmuted, at which point, please state your name and question. If you are audio only, and you'd like to ask your question verbally, dial pound two on your telephone keypad. You'll hear a notification when your line is unmuted, at which point, please state your name and question. You can also submit your questions in writing. Just remember to select all panelists from the dropdown menu in the chat panel before entering your question in the message box provided and sending it.

Meryl Silverman: All right, so far, we have one question in the chat, "Where can I get a copy of the slides?" I can share that we do have, as Scott mentioned, there are recordings of

the May 23rd and May 24th, as well as Monday, September 19th, webinar on our FSIS website, and the PowerPoint slides are shared there. Then after the recording of today's session will be available, that will be included. All the presentations use the same slides. The only difference are the questions, and so we're providing all the recordings in case people want to hear the different questions and answers.

Event Producer: I'm not seeing any hands raised in WebEx or on the phone.

Scott Updike: Well, if there's no additional questions, I will go ahead and pass it off to Aaron to present on appendix B. But just as a reminder, if you do come up with any additional questions for appendix A, you can ask that at the very end of the presentation.

Aaron Beczkiewicz: Scott. So shifting into 2021 Stabilization Guideline and Revised Appendix B. Next slide please. And so, again, before going into the specifics of the guideline, we wanted to set the stage for why we have the guideline. It is to help establishments support their stabilization processes. Stabilization is defined by FSIS as the process of preventing or limiting the growth of spore-forming bacteria capable of producing toxins, either in the product or in the human intestine after consumption. Stabilization processes typically include cooling and hot holding and establishments may support drying and fermentation, acidification as stabilization processes for products with a pH of less than or equal to 4.6 before cooling-

Paul Kiecker: ... Four products with a pH of less than or equal to 4.6 before cooling, products with a water activity of less than 0.9, three before cooling or products with other validated pH and water activity combinations.

Next. The primary hazards of concern during cooling and hot holding are Clostridium perfringens and C. Botulinum. The 2017 version also discussed bacillus series as another spore forming bacteria that may also be a hazard of concern during cooling and hot holding. We have removed much of this discussion in the revision because FSIS does not expect establishments to have additional support for bacillus series controls in their hazard analysis if they have already supported control of C. perfringens. In normal operating conditions, if C. perfringens is controlled, then bacillus series is not a concern. However, in extreme cooling deviations, it is possible for bacillus series to grow to high levels and should be considered during the product disposition, determination. Next slide.

This slide shows in more detail, some of the unique aspects of spore formers, such as Clostridium perfringens. Meat poultry products may become contaminated with clostridium during the slaughter are dressing process. Clostridium may also result from cross contamination in the processing environment when in sanitary conditions are present. Additionally spices and herbs can contribute to the spore count in raw formulated, cooked heat treated meat and poultry products. While cooking of meat and poultry products will

destroy vegetative cells of bacteria like salmonella S tech and LM, bacterial like C. perfringens and C. botulinum form spores that may survive cooking. These spores can grow into vegetative cells during cooling because they do not have competition from other bacteria and the temperature is in the danger zone for their growth. Therefore, the best control to stabilize heat treated products is rapid cooling to reduce the amount of time the spores can grow into cells.

The 2017 guideline clarified that products which are heat treated but not cooked to lethality need to consider the heating come up time in addition to the cooling schedule to limits spore former growth. Heating steps like smoking can support the growth of spore formers, but if the product does not reach lethal temperatures that kill the vegetative cells, the pathogen can grow to higher levels during cooling. This also applies to products which may be cooked to lethality, cooled, then heated again to sub lethal temperatures for browning or double smoking. Next.

As with cooking FSIS has performance standards for limiting C. perfringens and C. botulin growth in certain products. Again, codified performance standards are requirements in terms of what is to be achieved, not the means to achieve those ends. For products without a performance standard establishments are still required to support decisions in their hazard analysis. To support decisions in the hazard analysis, FSIS recommends establishments limit outgrowth to the same levels.

In other words, allow no multiplication of toxigenic microorganisms such as C. botulinum and no more than one log multiplication of C. perfringens during stabilization of fully cooked or partially heat treated products. Next. The 2021 stabilization guideline is designed to help establishments understand the biological hazards during stabilization, regulatory requirements associated with the safe production of stabilized heat treated and partially heat treated products, options establishments can use to prevent the growth of C. perfringens and other pathogens, processes that do not have validated research available and options establishments can use until research is available, recommendations for evaluating fueling deviations and resources for alternative support.

Next, the stabilization guideline also includes a summary of changes specifically the 2021 guideline specifies those products that are covered by the guideline and those that are not, clearly delineates which cooling options may be used for products with a full lethality and which may be used for partially heat treated products, added additional cooling options for certain formulated products provides journal articles for processes like bacon and scrapple includes critical operating parameters from older guidance for products included in a scientific gap similar to what Scott talked about for cooking and better describe steps for evaluating cooling deviations.

Next. As discussed within the guideline, FSIS has described three critical operating parameters for cooling processes. Time and temperature are familiar

to most people. The third parameter, pre-cooling conditions is a mixture of intrinsic product characteristics, such as salt pH nitrate and water activity, which affect outgrowth of spore formers. For example, higher salt content or lower water activity can inhibit C. perfringens growth.

Next. The various cooling options and associated critical operating parameters are provided in table one and table two. The cooling options in table one can be used for products that have been cooked to full lethality. As I'm sure many of you have noticed gray shading within tables one and two indicate options where critical operating parameters have changed or are new since the original 1999, appendix B. Option 1.4, which was originally provided in FSI directive 7110.3 has been included in the 2021 guideline. FSI directive 7110.3 has since been canceled as directives are intended to provide instructions to FSIS personal, whereas option 1.4 is guidance for industry.

We have also noted that full lethality can be achieved by following options in the FSIS cooking or alternative support. This includes products that are cooked lethally, but reclassified as not ready to eat. If appendix A is used establishments must address all critical operating parameters, including relative humidity, or provide a justification for why relative humidity is not addressed.

Next. One question we have gotten since the revision was issued is whether option 1.2 chilling could begin within 90 minutes, regardless of the temperature at the end of the 90 minutes. And the answer to this is no. The intention of option 1.2 is for chilling to begin when either the 90 minutes is up or product reaches 120 degrees Fahrenheit. This option has not changed and establishments always had to document when the product reached 120 in order to demonstrate the time component was met.

Next. As mentioned previously options, 1.5, 1.6 and 1.7 are new cooling options for products cooked to full lethality. These options were available in a public ask emphasized Q and A and are now incorporated into the 2021 guideline. Establishments can use the stabilization guideline as support for cooling product. According to these options, note that option 1.5 is similar to option 1.1, however, option 1.5 provides an additional 30 minutes of cooling time.

Using newer modeling programs FSIS was able to support extending the time product spent between 130 and 80 degrees by 30 minutes. Option 1.1 was kept in the guideline during revision so that establishments originally following this option would not have to change their parameters or support. An establishment that had been using option. 1.1 could certainly switch to option 1.5.

Next, the cooling options and associated critical operating parameters for products which are not cooked to a lethal time and temperature combination are provided in table two. Note that both options include heating come up time, the amount of time product spends between 50 and 130 degrees Fahrenheit as a pre-cooling condition. This is to ensure cumulative growth of C perfringens is limited to one log or less. You may notice that the cooling schedule for option

2.1 on this slide is the same as option 1.1 for fully cooked products, except for the addition of a one hour come up time limit.

This limit is included to address the potential for growth of Staph aureus and clostridial during both the heating come up time and cooling time since there's no lethality step in between. The new option 2.2 allows for up to three hours come up time if the product precooling conditions are met. This option was designed in response to individual ask emphasized questions we received from establishments looking for support for partially heat treated cured sausage that had a heating come up time longer than one hour.

Next. As mentioned in the previous slides, some of the stabilization options include precooling conditions. These are conditions that must be met in order to support cooling product according to that option. The intent is that these parameters are met precooling, but logistically some parameters may be monitored at different points. For example, nitrate and ascorbate or erythorbate levels may be calculated based on the ingoing formulated amount.

Brine concentration is calculated from the total salt content and total water content values obtained by a laboratory analysis of cooked and cooled product. We would not expect the brine concentration to change after it is cooled and logistically it is not possible to send in a sample pre-cooling. pH must be monitored after cooking prior to cooling, or the establishment must support how the monitoring location represents to the pH pre-cooling. And just as a note, I am using the terms monitoring, but it would be up to the establishment to determine how to incorporate these parameters into their system, either through a prerequisite program, CCP, or during the initial setup of their system with ongoing verification. These concepts are described in FCIs validation guideline.

Next. In terms of policy clarifications, the 2021 guideline has better clarified that products that are fully cooked, but reclassified to not ready to eat can follow any option.

We have clarified that temperatures referred to in tables one and two are internal product temperatures. However, establishments may provide support for monitoring surface temperatures of intact products, such as beef brisket or picnic shoulder that is not injected or vacuum tumbled. Products should still be cooled continuously. This is important because if the product is removed from the cooling medium before the internal temperature is cooled, the surface temperature may rise. We also clarified that if a process incorporates multiple full lethality treatments, the establishment needs to assess the growth of clostridial during the cooling step, following each individual lethality treatment and does not need to assess the cumulative growth over the multiple steps. This is not a change, rather we realize through individual ask FSIS questions that the language we used in the 2017 version was confusing. The language in the 2021 guideline better reflects what we always intended. Next.

I do want to take a moment to highlight two journal articles included in the guideline that may help establishment support cooling of partially cooked heat treated bacon and cooling of scrapple products. The Taormina and Bartholomew article was included in the 2017 version of this guideline, but many establishments were not aware of it.

Next, because we have received a lot of questions about the cooling of bacon products, I am also going to take a moment to highlight specific options. There are several options establishments can follow in cooling bacon, however, whether one is appropriate or not will depend on whether the bacon is partially heat treated or cooked to lethality. While a product may be cooked to lethality, establishments may reclassify the product as not ready to eat provided the product is not required to be RTE by a standard of identity. The slide has an overview of the options that can be used for both bacon that is partially heat treated and cooked to full lethality, which I will go into greater detail on the next slide.

Please note that establishments producing bacon must also consider permitted uses for nitrate and ascorbate or erythorbate in 9 CFR 424.22 and natural sources of these ingredients in FSI is directive 7120.1.

Next. As I mentioned, we have received a lot of questions about the options for bacon because there are several in the guideline and they depend on whether the bacon is partially heat treated or cooked to lethality. For partially. He treated smoked products, such as bacon establishments can follow the Taormina and Bartholomew article, which allows for a 15 hour cooling time. However, the establishment would need to address come up time and achieve specific formulation critical operating parameters. Appendix B also has a scientific gap that allows for a 15 hour cooling time with no heating come up time parameter provided the product is smoked and contains a certain amount of nitrate and ascorbate. You will notice this is similar to the Taormina and Bartholomew article, although that has some additional formulation parameters. For bacon cook to lethality establishments may follow option 1.3 in table one or scientific gap three for bacon products that achieve a lethal time temperature combination, but do not apply relative humidity. Depending on an establishment's process and product scientific gap four for immersion or dry cure products may also apply. Next.

In addition to the policy clarifications previously discussed FSIS has removed discussion of a waiver option for using a cooling process that allows up to two log growth of clostridial. Some establishments have worried they must perform sampling to use the one log cooling options, which is not true. We also found some establishments where using the two log cooling options without performing sampling or applying for a waiver of the applicable regulations. Since FSIS had not received any waiver requests and the information caused confusion, FSIS removed that guidance although establishments are still able to request a waiver. We have also received many questions around using natural sources of nitrate and ascorbate. We have updated the guidance to include

detailed information on their use. Next. Specifically, we have clarified that natural sources of nitrate like celery powder are not considered a curing agent, but this is currently a labeling distinction.

FSIS intend to conduct making on these requirements as we have been petitioned on this issue. Some sources such as cultured celery powder are considered as antimicrobials along with a natural source of ascorbate and may be used to meet option 1.3. These antimicrobials are listed in FSI directive, 7120.1. Cultured celery powder is typically used as an antimicrobial, not a flavoring agent because the ingredient is cultured specifically to reach a standardized concentration of nitrates. For this reason, if used as an antimicrobial, it must be declared on the label and cannot be labeled as a natural flavor. FSIS recommends that establishments use natural sources of nitrate containing preconverted nitrate because the quantity of nitrate in these sources is known. When using pre converted nitrate establishments should request the information from their supplier regarding the nitrate level in each lot of product, for example, by receiving a COA and calculate the amount of natural source needed to achieve the appropriate nitrate concentration from each lot, as it will vary or receive formulation information from their supplier if the concentration is standardized from lot to lot.

Please note that natural sources of nitrate cannot currently be combined with synthetic or purified ascorbate or erythorbate and vice versa. A natural source of nitrate should be combined with a natural source of erythorbate while a synthetic or purified nitrate should be formulated with a synthetic or purified form of ascorbate or erythorbate.

Next. As with the cooking guideline under appendix A, FSIS became aware of several types of processes, which had been using appendix B as support that were not supported when the agency clarified the guidance's limitations in 2017. Additionally, the agency could not identify scientific literature to support certain products and processes. FSIS encourages establishments to conduct challenge studies when appropriate, however, the agency realizes it may not be cost effective for every establishment to conduct individual challenge studies. Therefore FSIS posted research priorities on its website to communicate clear research needs with USDA, ARS and academic researchers. FSIS is calling these specific processes and the research needs scientific gaps. To share information in a timely manner, FSIS is updating the guidance to address public comments received on the 2017 guideline. Recognizing that gaps remain in knowledge related to certain cooking and cooling processes. While waiting for research results FSIS is allowing establishments to continue using the older operating parameters.

There is a vulnerability that these parameters have not been validated to achieve lethality or controlled spore form or growth using microbial challenge studies or published researchers, but researchers need time to perform such studies.

Next. For appendix B, these vulnerabilities include that the processes have not been validated to address all hazards of concern. If a process deviation occurs for a process that is included a scientific gap, it is unlikely an establishment would be able to identify adequate support for product safety without performing product testing. If FSIS or the establishment collects an RTE product sample that is positive for a pathogen or the product is implicated in a food safety investigation, FSIS would verify as part of the corrective actions, but the establishment can demonstrate that inadequate lethality or stabilization was not the root cause of the positive sample or the confirmed illness or outbreak, which it would need to do if it wants to continue to use the older recommendations. As additional data becomes available, FSIS will change the recommendations for processes that fall under one of these scientific gaps. We are not going to go into details on recommendations that we have made for each gap to reduce the vulnerability but we want establishments to be aware that these recommendations are there, but are not required. Next.

And so scientific gap one in the stabilization guideline applies to large mass non-intact products that cannot cool quickly enough to follow the revised options. In general, these products had been following the older parameters and monitoring that product cooled from 120 to 55 degrees Fahrenheit in six hours or less. The older guidance also noted that products that take longer than one hour to cool from 120 to 80 were likely to exceed the performance standard, however, this parameter was not clear and is difficult to meet for large products. Processes that meet this gap include those in which product is cooked to full lethality, not intact and due to its size cannot cool quickly enough between 120 to 80 degrees Fahrenheit. For these products, establishments can continue to follow the older parameters where chilling within 90 minutes after the cooking cycle is complete. Product under this gap would be cooled from 120 to 55 in six hours or less with continuous cooling to 40.

Remember cooling begins within 90 minutes after the cooking cycle is complete or when the product reaches 120, whichever comes first. This gap can be referenced in the hazard lyses as scientific support for why the time large mass not intact products spend between 120 to 80 is not addressed in this process. Establishments must still follow the older parameters of time and temperature if following this option.

Next. Scientific gap two applies to partially heat treated, smoked products that contain nitrate and ascorbate or erythorbate, but have long come up time and cooling times. The 1999 version of appendix B stated that the cooling option for products containing nitrate, that is the 15 hour cooling option, was for RTE products. After the 2017 revision FSI learned that establishments were using this option for not ready to eat, partially heat treated products in particular smoked products, such as bacon or ham.

These products had long heating come up times along with 15 hour cooling time but that original option was not validated a partially heat treated product. Processes that meet this gap include those where the product is partially heat

treated, smoked and contains sufficient nitrate and erythorbate or as ascorbate per the gap. For these products, establishments can continue to follow the older parameters where product is cooled from 130 to 80 in five hours or less and 80 to 40 in 10 hours or less for no more than 15 hours total cooling time. There is no come up time parameter for this gap.

Next. Scientific gap three applies to smoked bacon cooked without relative humidity. FSIS is aware that bacon processors will often cook to lethality, but reclassify the bacon as not ready to eat in order to use the slower cooling option. FSIS has learned that these processes have not historically addressed relative humidity and the role of relative humidity related to C. perfringens has not been evaluated for bacon. Processes that meet this gap include those where the product is cooked to a lethal time and temperature, but relative humidity is not addressed, been smoke and contains sufficient nitrate and erythorbate or ascorbate per the gap.

For these products establishments can continue to follow the older parameters where product is cooled from 130 to 80 in five hours or less and 80 to 40 in 10 hours or less for no more than 15 hours total cooling time. There is no heat come up time for this parameter. This gap can be referenced in the hazard analysis of scientific support for why heating come up time is not addressed in such a process and why the 15 hour cooling time can be followed, even though product was cooked without relative humidity. Establishments must still follow the other parameters of time and temperature if following this option.

Next. Scientific gap for applies to dry cured products that contain nitrates or nitrate and use equilibration time instead of a cure accelerator. We know from the literature that quick cured products require a cure accelerator for nitrate to have a food safety effect and in turn allow for the slower 15 hour cooling time. We expect that equilibration time acts similarly, but no research has validated the length of equilibration time, for example, whether two, three or more days are needed for a food safety effect. Processes that meet this gap include those in which the product is fully or partially heat treated immersion or dry cured, contains sufficient nitrate or nitrate per the gap, and has a minimal equilibration time of at least two to three days. For these products establishments can continue to follow the older parameters where products were cooled from 130 to 80 in five hours or less and 80 to 40 in 10 hours or less for no more than 15 hours total cooling time. There is no come up time parameter for this gap. This gap can be referenced in the hazard analysis of scientific support for why heating come up time is not addressed in such a process and why the 15 hour cooling time can be followed without the addition of ascorbate or erythorbate. Establishments must still follow the other parameters of time and temperature if following this option.

Next. Scientific gap five applies to products that contain nitrate and use equilibration time instead of a cure accelerator, but do not have brine concentration greater than 6%. After the 2017 version of this guidance was

issued, FSIS became aware of at least one establishment that had met these criteria.

Paul Kiecker: Became aware of at least one establishment that had met these criteria, but was following an older recommendation for 20 hours of cooling time with at least 120 parts per million nitrate and at least 3.5% brine concentration, FSIS removed this older recommendation because validated pathogen modeling programs have indicated these parameters may result in greater than two log growth of CFR engines. This may be because these products do not contain a cure accelerator, but our understanding is that equilibration time is used by these processors instead. As with gap four, there is no research currently available that is validated the length of equilibration time. Processes that meet this gap include those where product undergoes any heat treatment, is pumped with nitrate or nitrate, has a brain concentration of greater than 3.5%, but less than 6% and has a minimal equilibration time of at least two to three days.

For these products, establishments can follow option 1.4, where products is cooled from 120 to 40 in 20 hours with a continuous drop after. This gap can be referenced in the hazard analysis as scientific support for why the 20 hour cooling time can be followed without the addition of ascorbate or erythorbate. Establishments must still follow the other parameters of time and temperature if following this option.

Next, the final gap, scientific gap six applies to scalded offal that cannot cool quickly enough to follow the new options. After the 2017 revision of this guidance, FSIS has learned that establishments were scalding edible offal to temperatures similar to a partial heat treatment. However, these establishments could not follow the options for partially heat treated product now contained in table two. Processes that meet this gap include those in which product is edible offal, which is partially heat treated or scalded.

For these products, establishments can use the 20, the stabilization guideline to support cooling of scalded offal to 45 degrees in less than 24 hours. Similar to Carcas chilling recommendations. This gap can be referenced in the hazard analysis as scientific support for why cooling scalded offal in this manner. Establishments must still follow the other parameters of time and temperature is following this option.

Next. This table is again intended to better explain the difference between scientific gaps and the list of products not covered by this guidance. There are some products where researcher outbreaks demonstrate FSIS guidance is insufficient to result in safe product. These products cannot use FSIS guidance as scientific support and must identify alternative support. An example is Fish to the Order Siluriformes, as appendix B, was not developed for fish products. There are other products where there's no evidence showing any imminent food safety concern, but current parameters cannot be applied. Products that fall under these scientific gaps can use the stabilization guideline as support. The scientific gap section of this guideline includes the 1999 appendix B

parameters that can be applied. For example, large mass non-intact products that cannot cool to 80 degrees in one hour or less, but can cool to 55 or less in six hours.

Next, in addition to the various cooling options and scientific gaps, the stabilization guideline also includes information on cooling deviations. Specifically the guideline addresses how to use pathogen modeling and sampling to determine product disposition after deviations, as well as how to use sampling and recooking to support product disposition.

Next, this guideline also contains information on how to evaluate the results of a cooling deviation using pathogen modeling when product is under establishment control. The guideline includes information about the validated cooling models that are available online. All of the models are free and easy to access although some may require a sign up for a login. Establishment that the need help using these models may seek assistance from state university extension specialists or HACCP coordinators and FSIS recently revised its HACCP validation information webpage under the section HACCP coordinators to include an updated listing of contacts. Depending on the amount of predicted growth establishments may have different options for disposition.

FSIS always recommends establishments to perform pathogen modeling to assess the severity of a deviation. As noted on the slide, if there is any possibility of C botulinum multiplication, which in modeling terms means a greater than 0.3 log growth as shown by a modeling program, then the product should be destroyed. In other words, there are some cases where sampling would not be an option. The guideline provides additional detail on each of these options. So, we recommend it be reviewed each time there is a deviation.

Next, to summarize FSIS revised its stabilization guidelines and cooking guidance in 2021 in response to public comments. The stabilization guideline contains critical operating parameters for hot holding and stabilization and updated pathogen modeling guidance for deviations. As with the cooking guideline, the stabilization guidelines, specifies products that are covered by the guidance and those that are not. It also includes older parameters for some common cooling processes that can be used until further research is conducted because there is insufficient evidence showing imminent food safety concern. Establishments that utilize previous versions of appendix B as support should either update to the 2021 guideline or identify alternative support by December 14th, 2022. Also, as a reminder, FSIS did provide will be providing instructions to FSIS personnel prior to December 14th, 2022.

Next. Again, before we get to questions, we also wanted to share the takeaways on appendix B. We shared with our inspection program personnel during their webinars in August, so that everyone is receiving the same information. Scott already covered how ITP are to make establishment management aware of the revised guideline and that FSIS will provide further instructions to IPP before the December implementation date. We want to be sure that IPP are aware that the

options in the body of the 2021 guideline may be used to support by establishments producing products cooked to lethality, and keep heat treated products to meet element one of validation to support hazard analysis decisions. Pooling options from previous versions of the guidelines and the canceled directive. 7110.3 are included in the revision. There are some changes to the original options, which are, we have shown in gray in the guideline and on the previous slides. Also, several new options have been added that have been in knowledge articles, previously.

Cooling options for ready to eat and not ready to eat products subjected to a fully lethality during production are included in table one of the guideline. Cooling options for partially cooked products are included in table two of the guideline and include heating come-up-time as a critical operating parameter. Establishments are not required to follow the parameters in appendix B and may use a customized process or alternative support.

Next establishments using common cooling processes that use the 1999 version of appendix B, but cannot achieve the heating come-up-time for partially heat treated products, cooling time temperature or pre-cooling conditions in the revised guidelines may be able to use the scientific gap as support for not addressing the critical operating parameter.

There is a vulnerability with using the scientific gap as support for not addressing the critical operating parameter, but FSIS has determined there is not an imminent public health concern, and that establishments can use the scientific gap of support until more research is conducted.

As indicated earlier, if FSIS or the establishment collects are ready to eat sample that is positive for a pathogen or the establishment is implicated in a food safety investigation. FSIS would verify as part of the corrective actions that the establishment can support inadequate stabilization was not the root cause, if it wants to continue to use the older recommendation.

Next. As Scott indicated for appendix A, IPP are being instructed to refer questions to their supervisor or ask questions as needed through ask FSIS and per notice, 59-21, IPP are being instructed to refer questions using the HACCP deviation asset validation as the inquiry type or by telephone. Establishments can also submit their questions using a similar manner through Ask FSIS using the same inquiry type. We have provided the link for Ask FSIS web form on this slide.

Next. With that, thank you for your time and attention. I will ask the event producer to again, remind attendees how they may submit questions through the chat or over the phone on. You're welcome to ask questions on either appendix B or appendix A.

Meryl Silverman: All right. As we move, once again into Q and A, feel free to place yourselves in the verbal question queue by dialing pound two on your telephone keypad, if you're audio only, or by using the raise hand icon in WebEx. You'll hear a notification when your line is unmuted, at which point, please state your name and question. You can also continue to submit your questions in writing, using the chat panel on the right hand side of your screen. Just remember to select all panelists from the dropdown menu before submitting your questions.

Tennetta Hazard: There are a couple of questions in the chat. The first is a comment asking for the link to the slides to be posted in the chat. Then, for the first question, "can a gap be used for relative humidity for bacon in appendix A? If so, what would be the validation process?"

Aaron Beczkiewicz: So it is unclear to me whether this is asking about using a gap from appendix A to support a bacon process, or if you're referring to supporting a bacon process that you're cooking to lethality, and then, but not addressing relative and talking about a scientific gap in appendix B. In general, if you are cooking a bacon product to a lethal time temperature combination, but not addressing relative humidity. You're looking to support that you can use option 1.3 in appendix B to cool that product. You could reference scientific gap three in appendix B before that process. In terms of validation processes, and whether a process, how to go about doing that. I would recommend referring to the HACCP systems validation guideline, which outlines how establishments can go about validating both the implementation or the design and the implementation of a HACCP system. If you have specific questions about that validation beyond that, I would recommend submitting those to Ask FSIS because it might be better for us to address it through that venue.

Meryl Silverman: Yeah. I'll just add to what Aaron said, because I think the person asking the question just clarified a little bit more. If they are following that scientific gap, what would the validation process, if any look like and yeah, I think Aaron has a great suggestion to refer to the validation guidance. Really the key, whenever we hear the word validation, we always try to be specific that validation has two parts. So it's important to be specific about which part you're asking about. The first part of validation is the scientific or technical support. So the idea here is that the scientific gap would be used to meet that first element of validation. Really what we're recommending is that establishments reference the scientific gap as support for their decision making in the hazard analysis. So this would be your justification for why you're not addressing relative humidity, that way when OFO verifies your hazard analysis and scientific support clear to them why you're not addressing that critical operational parameter.

We put this scientific gap in appendix B because really not addressing relative humidity impacts which stabilization option you're able to follow. Because again, the table one is for products that are cooked to lethality, that would be addressing time temperature relative humidity. Table two is for those partially heat treated products. So again, that scientific gap would be your element one, a validation to support your justification for not addressing relative humidity.

Whether you need to gather new implant validation data would depend on whether there's any changes to your other critical operational parameters, like time and temperature as a result of referencing that gap. But you don't need to gather implant validation data related to relative humidity because the gap is your support for not addressing it. So there's not going to be any implant validation data needed for relative humidity because you're not going to be addressing that critical operational parameter citing that gap.

So hopefully that answers that question. But please go ahead and let us know in the chat, if that's not clear or if it doesn't, or as Aaron said, can submit this specific question and Ask FSIS. Then I did just want to mention, I did post the links to the May 23rd and May 24th events pages in the chat to all attendees. So hopefully if you're able to see that those links both include under it's called the media library, a link to the PowerPoint presentation. Again, it's the same PowerPoint presentation as we're sharing today. If you're not able to see the link, then our WebEx moderator should be able to help you with that. I'll turn it back over to Tennetta.

Tennetta Hazard: Next question. What is meant by equilibration time?

Paul Kiecker: So, equilibration time is the amount of time over which when you're curing a product, either with salt or nitrate or nitrate, that the cure component or the salt or the nitrate or nitrate is essentially migrating into the meat product and becoming dispersed throughout the meat product. So, that's the time that it takes to have that component actually permeate the product and provide the food safety effect that it's being used for.

Tennetta Hazard: Last question. Is it correct that culture celery powder cannot be used as a curing agent?

Paul Kiecker: So as discussed on the slide discussing the specific considerations of natural sources versus purified or synthetic, this is currently a labeling distinction. If you are using cultured celery powder to cool products according to one of the options in appendix B, and it's a natural source of cultured celery powder, then it would be considered an antimicrobial under 7120.1. Direct of 7120.1.

Tennetta Hazard: Those are all the questions from the chat.

Paul Kiecker: With that, I'll ask Scott to go to the next slide. So, just as we had mentioned before, just providing a quick update on the scientific apps and progress that FSIS is making towards addressing these scientific gaps.

Next. So during the presentation of appendix A and B, we shared several scientific gaps for which we could not identify scientific literature as support and are seeking more research. To address these common processes, which lack readily available scientific support, FSIS has identified and communicated scientific gaps and is working to facilitate filling these gaps. FSIS posted research

priorities on its website to communicate clear research needs with USDA's agricultural research service and academic researchers. We are excited to share some updates on the progress made. FSIS set up an interagency agreement with the agricultural research service to complete several studies related to the scientific gaps.

The group has prioritized the research and ARS has started studies related to determining the lethality of Listeria monocytogenes and Salmonella in low water activity, cured meat products, such as country cured hams and identifying acceptable lethality treatments for baked goods that contain raw meat or poultry components. There's also a USDA funded project in which the American association of Meat Processors is assisting Michigan state university and the University of Wisconsin Madison with a large multi-year research project related to some of the scientific gaps in appendix A, related to identifying alternatives to FSIS's relative humidity options for ensuring service lethality. As additional data becomes available, FSIS will update the recommendations for these scientific gaps, with the latest available scientific support. We are planning on having some updates for you on these gaps in the next year. In the meantime, establishments can continue to use the older parameters included in the scientific gaps in appendix A and B as part of the scientific support for decisions in the hazard analysis, as we discussed earlier.

Next. Another update we would like to share is related to FSIS' Clostridium perfringens market basket survey that has been designed to address a stabilization research gap identified by FSIS related to the cooling of large mass non-intact products. Comments on the 2017 revised appendix B guideline stated that the large mass non-intact products such as RTE turkey breast and roast beef cannot be cooled quickly enough to meet the recommended cooling options. To address this gap, FSIS conducted a study between may and September of 2021 to assess levels of C. perfringens in federally inspected, RTE meat and poultry products sold at retail locations. This study was announced in a May 2021 constituent update. The samples in the study were collected at retail locations and analyzed by the food emergency response or FERN laboratories.

The results were blinded to FSIS and have been provided to us six months after completion of the study in March, 2022. Initial results indicate no concerns with the sample results, as almost all results were below the limit of detection for C. Perfringens. We are analyzing the study results and will use them to assess whether changes are needed to the cooling recommendations in appendix B for these products. Or we may find that a larger, more comprehensive baseline study is needed. We plan to report the results in aggregate on the FSIS website and in the literature. In the meantime, we will maintain the 1999 cooling options for specific processes with scientific gaps, which would include the 1999 cooling option two that is commonly used as support for cooling of these large mass non-intact products.

Next. Here's just a screenshot of the website where FSIS has posted our research priorities to communicate clear research needs with USDA, ARS and academic researchers. We encourage researchers to review these gaps and conduct studies to address them. Again, as additional data becomes available, FSIS will update the recommendations for these gaps, with the latest available scientific support.

Next. With that again, if you do have any other questions, we will welcome more open questions. You are also welcome to submit questions after this through Ask FSIS.

Meryl Silverman: Once again, if you'd like to ask your question verbally. You can do so by selecting the raise hand icon in WebEx, or by dialing pound two, on your telephone keypad. You'll hear a notification when your line is unmuted. At which point, please state your name and question, or you can submit your questions using the WebEx chat feature. Just remember to select all panelists from the drop down demo menu before submitting your question.

Tennetta Hazard: Again, there are no questions in the chat.

Paul Kiecker: Well, thank you everyone for attending today. As we had mentioned, this specific webinar was recorded along with the other three webinars that were held for industry, and those are all available on the FSIS events page including the transcripts and the questions from each of those sessions. So again, you're able to access those. Meryl provided the links in the chat for that. You are welcome to submit questions through Ask FSIS and thanks for your time today.

Moderator: That concludes our conference. Thank you for using event services. You may now disconnect.