Speaker 1:	Ladies and gentlemen, welcome, and thank you for joining today's Revised Appendix A and B Guidelines webinar. Before we begin, please ensure that you have opened the WebEx participant and chat panels by using the associated icons located at the bottom of your screen. Please note, all audio connections are currently muted and this conference is being recorded. You are welcome to submit written questions throughout the webinar, which will be addressed at the Q and A session of the webinar. To submit a written question, select all panelists from the dropdown menu in the chat panel, then enter your question in the message box provided and send. To ask a question via WebEx audio, please click the raise hand icon on your WebEx screen. This is located above the chat panel on the right. This will place you in the question queue. If you are connected to today's webinar via phone audio, please dial pound two on your telephone. Key to enter the question queue. If you require technical assistance, please send a chat to the event producer. With that, I will turn the webinar over to Paul Kiecker, administrator. Paul, please go ahead.
Paul:	All right. Thank you very much. I really wanted to say welcome to everyone and also remind you that this webinar is set up specifically so that industry and establishments can get their questions and concerns addressed on the new and revised Appendix A and B guidelines that are out there. So make sure that you use this opportunity to ask questions and get the answers to those questions. We realize that there are some significant changes that go along with the revised Appendix A and B, and the changes are to make sure that the guidelines that people are using are still able to produce safe product. Things change over time, and that's the reason for the revised Appendix A and B. The request for these webinars actually came through industry and people have asked, at different meetings that I've been at, different round tables, "Are we going to have any type of training or anything on Appendix A and B?"
	So that's what this is intended for. So you asked for these webinars, we're providing the information to you. So make sure that you use the time here to get those types of things addressed. I also brought up, on the all establishment call earlier, that if you have specific concerns and you want someone to take a look at what it is that you're doing, how that relates to Appendix A and B, reach out to the district office so that they can have an EIO come out, take a look at what it is that's going on in your facility, see if there's any changes that are going to be expected to make, what the options are for you. So please don't wait until implementation date and then find out that something is not going to be supportable. So please be proactive on any changes, finding out any questions that you have related to Appendix A and B. Again, I really want to say thanks for taking time to be on the webinar today. And with that, I'll turn it over to Merrill to start off with the slides. Thank you very much.
Meryl:	Great. Thank you so much, Paul. My name is Meryl Silverman, and I'm a senior food technologist with the office of policy and program development. So you just had a welcome from Paul Kiecker. I'm going to then start us off with an overview of the changes to the guidelines, then I'm going to review the 2021 FSIS cooking guideline, or revised Appendix A. And as Paul indicated, we're

going to be having a lot of opportunities for a open question session. I'm then going to turn it over to Scott [inaudible 00:04:56], also in the office of policy and program development, to review the stabilization guideline or revise Appendix B. And then at the end, I'll give you some updates and next steps on our scientific gaps. Again, leaving time for open questions after each topic.

So very briefly, we want to share the history of the guidelines, which you may be familiar with, but we find it helps to explain how we came to the 2021 revision. So initially, FSIS had prescriptive commander control, cooking and cooling regulations that defined how, step by step, to cook and cool certain products such as roast beef that have been associated with outbreak. When FSIS moved to HACCP, it removed those requirements and instead implemented solidified performance standards that set requirements for the amount of reduction or outgrowth allowed. It didn't require particular ways to achieve those standards. FSIS only implemented performance standards for the same products historically associated with outbreak. Along with those performance standards, FSIS issued guidelines in appendixes to the final rule called Appendix A and B. These provided optional safe harbors taken from the command-andcontrol regulations intended to help establish producing products under the performance standards comply. Over time though, the guidelines became used as support for many more products than originally intended, which led us, in 2017, to try to clarify their use and now with these 2021 revisions.

So in terms of the 2017 guidelines, which were issued in June 2017, we issued revised versions of Appendix A and B. And when the guidelines were reissued, we received a number of comments on them that led to a delay in verification. FSIS responded to all of the comments in the Federal Register that was issued in December 2021, announcing the 2021 revised and final versions of Appendix A and B. Many comments related to common cooking and stabilization procedures for which establishments have used Appendix A and B as support in the past, even though these processes couldn't achieve the critical operational parameters included in the revised guidelines. And so you'll hear today how we've addressed those comments.

So these comments really 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's current thinking on these topics and establishments that utilized 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 establishments may need to gather new initial implant validation data should the change in scientific support results in a change to the critical operational parameters being implemented.

So, as you've heard, we recommend establishments start considering the changes now. Along with the guidelines, FSIS notice 59-21 was issued on December 14th. This notice instructs inspection program personnel, or 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 also provides instructions for enforcement, investigation, and analysis officers, or AIAOs, when performing food safety assessments in establishments using FSIS's Appendix A or B as scientific support. The notice also includes attachments with changes from the previous versions of Appendix A and B. And we also indicated FSIS will provide further instructions to its personnel before the implementation date of December 14th, 2022. We are also planning on providing webinars to IPP, along with its webinar for industry.

So with that, now I'm going to start talking about the 2021 cooking guideline, also called revised Appendix A. And again, we'll have time for questions after this section. So before going into the specifics of the guidance, we wanted to set the stage for why we have the guideline, and it's really to help establish and support their lethality treatment, specifically cooking. And lethality is defined by FSIS as the process or combination of processes that ensures a 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 we think of is cooking. So really 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 the other processes, FSIS has a guideline with food safety lessons from a 2011 Lebanon bologna outbreak. And this guideline can be applied to other semi-dry fermented sausage products. We also recently updated our house of validation webpage under the section house of validation by product to include journal articles and other peer reviewed scientific information that can be used as scientific support for the lethality treatments of fermented, slat-cured and dried product. In addition to the listing of these support documents, we included links to electronic journal articles when possible.

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

FSIS has defined and codified the log reductions of Salmonella that must be achieved by the lethality treatment to ensure specific products are safe. Products that have codified performance standards include roast, cooked and corn 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 Salmonella survives on the finished ready to eat product. FSIS guidance can be used to ensure Salmonella log reductions are achieved for products 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 these biological hazards during cooking meet the codified regulatory performance standards and ensure the safe production of cooked, ready to eat products. The guideline has options establishments can use to achieve lethality of Salmonella and the other pathogens I discussed. 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 such as journal articles, 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 guidelines. The goal is to help establishments understand how they are impacted by the revision, because remember, if an establishment used the 1999 or 2017 versions of Appendix A, they have until December 14th, 2022 to update to the new version or identify alternative support. One thing the revision does is specify those products that are covered by the guidance and those that are not, and I'll talk more about them. It also includes the food safety significance of the relative humidity recommendation. It specifies relative humidity should be addressed for all cooked products, unless the establishment can support, it does not need to be addressed. It provides additional resources for selecting a relative humidity option, even though those options have not changed. And it provides more information about situations when relative humidity does not need to be addressed, including that natural casings maintain relative humidity. It also includes critical operational parameters from the 1999 guidance for products included in a scientific gap. And again, provides more details for evaluating heating deviations.

Again, one thing the guideline does, which I mentioned, is address the products covered because this was something that was not entirely clear. Specifically, the guideline addresses lethality of pathogens, such as Salmonella and meat and poultry products by heat treatment or cooking, including for products that are cooked to lethality but classified under a not ready to eat passive 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 9CFR 301.2 and 9CFR 381.1, 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 also be very clear on the products that are not covered. As again, we've seen over the years, establishments were applying FSIS guidance to products it was not intended for, and that was causing a potential food safety

hazard. These products include the following and, where possible, we provided alternative support. For example, fish of the order Siluriformes are catfish. FSIS guidance was not validated for fish, but we included a link to FDA's fish guidance, which has cooking recommendations that can be used. Another product are pork rind pellets FSIS cooking guidance does not apply to the cooking or rendering of pork skins into a pellet, which is a very different process than cooking something like a roast. But we did include that establishments may use the cooking requirements in 9CFR 94.8B4 as support for cooking pork skins into a pallet.

FSIS cooking guidance also does not apply to the rendering of animal fat, such as lard and tallow, which due to the high fat content, generally need to reach higher temperatures and longer dwell times to achieve the same reductions in Salmonella. However, we do indicate that cooking requirements for rendering in 9CFR 315.1A can be used as support for the lethality step. We also noted here in response to some ask FSIS questions about hot filling, and although rendered lard and tallow use Appendix A to support lethality, it can still be used to support hot filling temperatures to consider a product not post lethality exposed. FSIS cooking guidance also does not support lethality for a process that relies on drying alone, such as biltong or for a process where the drying step comes before the cooking step, where humidity is not applied. So this could be something like 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 dry products, FSIS cooking guidance does not apply to those products that are fermented but not cooked or self-care products. I mentioned previously that we have a guideline for Lebanon bologna and other semi-dry fermented products, and also about our half of validation webpage under half of validation by product has been updated with journal articles for these products. And then finally, Appendix A does not cover partially heat treated, not ready products. We notice some establishments were cooking products to partial heat treatments, such as 145, with no dwell time and citing Appendix A even though Appendix A does not cover products that are partially heat treated. Establishments though can use the guidance in FSIS's Appendix B for these products. And as you'll hear Scott talk about, the guidance addresses both the heating come up and cooling time for partially cooked products.

So in terms of the Appendix A recommendations, it identifies three critical operational parameters to ensure adequate lethality when cooking meat and poultry products. These are time, temperature and relative humidity, and I'll describe these more on the following side. So the first two parameters I want to focus on are: time and temperature. And in particular, we're concerned about internal endpoint temperature and hold time, as well as the heating come up time. That's the time the product is between 50 and 130 degrees while it's heating up. So more specifically, in terms of heating come up times, time and

temperature is used to monitor come up time to ensure staph aureus outgrowth is controlled. The 1999 version of Appendix A mentioned a potential hazard, it's come up time was longer than six hours, but didn't clearly describe it as a critical operational parameter.

Since the 2017 clarified the come up time limit, we've heard that six hours can be difficult to meet for some product. So we've addressed that by explaining how establishments can support custom time and temperature parameters using alternative support and also by identifying a scientific gap. I'll discuss this in a lot more detail, but in short, a scientific gap is a common cooking or cooling process which had been using Appendix A or B as support, but could not follow the new parameters. These are products for which there's no imminent public health hazard, but there's also no scientific support we can provide. For these processes, establishments can continue to cite the older parameters in the scientific gap of support for their process. So in this case, for the heating come up time, establishments can use the scientific gap of support for not addressing heating come up time for products such as ham and brisket that are too big to physically meet the recommendation to limit the come up time to six hours or less between 50 and 130 degrees until new research can be conducted.

And at the end of the presentation, I'll discuss progress FSIS and others have made on filling these scientific gaps. In terms of internal endpoint temperature and hold time, fees 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's the older poultry recommendation to cook to 160 Fahrenheit or the newer tables for chicken and Turkey that take into account fat. Again, the cooking times and temperatures have not changed. And for the poultry time temperature tables, if an establishment does not know the fat content, FSIS recommends using the worst case scenario of 12% fat in the table. We've also added more detail about monitoring, and this is in response to a number of recalls of undercooked products where the establishment met their critical control point critical limit, but had shipped uncooked product.

What that indicates is that the monitoring frequency was not proficient to detected deviation. So we've added guidance to ensure that cooking procedures are designed to ensure all products in a batch or a lot achieve lethality, and that monitoring procedures should be designed to detect a deviation when it occurs. Establishments should carefully consider the selection of the critical limit, as well as the design of the monitoring procedures. And we've included lessons learned from several of these recalls related to insufficient monitoring. So that's information about temperature and time. The other critical parameter for cooking is relative humidity. And scientific research has shown moisture is important to [inaudible 00:22:22] on the surface during cooking. And it does this in two ways. It keeps the surface hot by preventing evaporative cooling, and it prevents defecation in pathogens from developing heat tolerance. Salmonella in particular is known to become more heat tolerant when it's dried as a part of the cooking process.

So we've tried to illustrate this concept here and why it's important to ensure there's moisture in the environment. And really simply when you get too hot, you produce sweat. And when that sweat evaporates, it cools you down through a process called evaporative cooling. As the sweat evaporates, it takes heat with it and cools the surface down in the process. So really this process of evaporation equals cooling. Now consider sweating in a tropical environment where there's high humidity, you feel wet, sticky, the air's heavy, the air has too much moisture for you to sweat to evaporate, so you stay hot. If you were in a desert, the dry heat would allow your sweat to evaporate, cooling your skin down. And the same thing actually happens to meat and poultry cooked in an oven. If the heat is dry, moisture evaporates, letting the surface stay cool, so cool bacteria may not be killed on the surface. 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.

So really the first step toward putting these parameters together is to choose a time temperature from the appropriate table. There are two tables for meat, two for poultry. Establishments must choose the table that matches their product and the targeted reduction. The next step then is to pick a relative humidity option. And this table clearly summarizes the relative humidity options and when they can be used. And note, these are all consistent with the 1999 version. We didn't make any changes to the options themselves, just how they're presented. Both the 1999 and 2017 guidance describes several situations which do not need to address relative humidity, and these 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 that will rapidly heat the surface, and activating bacteria before they can dry out. An example is heating on a grill or over a direct flame.

We had gotten a lot of questions around small mass products and when relative humidity does not need to be addressed. So what we've done is better clarify all products should address relative humidity unless they fall into one of these two groups. We also have a number of scientific gaps, which I'll talk about, an establishment can use to support relative humidity does not need to be addressed while research is conducted. Establishments who cook using one of these methods can support, they do not need to address or monitor relative humidity as part of their procedures and hazard analysis decision making.

We also discussed in the guidance that if an establishment wants to apply an alternatively found, for example, a five log reduction of Salmonella and meat, as opposed to a six and a half log reduction, they must provide additional support, and the guideline includes examples of such support. The guideline had also discussed detailed recommendations related to baseline sampling, but we've removed this information because it caused a lot of confusion and establishments only needed to do food sampling when they wanted to do something different to support an alternative lethality. Establishments following our six and a half log table do not need to do such sampling. And so, again, we've removed this recommendation since it caused confusion. We also address

the ingredients that are added after the cooking of the meat or poultry component. Establishments must consider any potential food safety hazards at the step in the process where the non-meat ingredient is received into the food safety system. Establishments should have letters of guarantee, certificates, analysis, or other information such as sampling to support the safety of the ingredients when they're added to a meat or poultry component after those have already undergone their lethality treatment.

So I mentioned that after the 2017 version of the guidance was published, FSIS became aware of several types of processes which had been using Appendix A and B as support, but were not supportive when the agency clarified the guidance's limitations. Additionally, FSIS could not identify scientific support to support such certain processes. FSIS encourages establishments to conduct challenge studies when appropriate. However, we also realize it may not be cost effective for every establishment to conduct individual challenge studies. Therefore, we posted research priorities on our website to communicate clear research needs with ARS and academic researchers. We're calling these specific processes in the research needs, scientific gaps. And so to share information in a timely manner, we're updating the guidance. But while waiting for the research results, we're allowing establishment to continue to use the 1999 version operating parameters by including them in these scientific gaps.

So establishments using older versions of Appendix A and B still need to update to the newer version. And there is a vulnerability in that these options have not been validated to achieve legality or controls former outgrowth using research. But again, 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. And again, at the end of the presentation, I'll discuss progress FSIS and others have made on filling these research gaps. So I mentioned there is a vulnerability in following the scientific gap, but I want to be clear that establishments can use these scientific gaps of support for decisions in their hazard analysis. We just wanted establishment to be aware that the processes have not been validated to address all hazards of concern. The original research used to develop these critical operational parameters was performed on only the few products covered by the performance standards.

So if a process deviation occurs for a process that's included in a scientific gap, it's unlikely an establishment would be able to identify adequate support for product safety without performing product testing. So this would be something an example of a power failure, or other type of deviation. Also, if FSIS or the establishment collects the RTE sample, that's positive for Salmonella or the establishment's implicated in a food safety investigation related to Salmonella, FSIS would verify, as part of corrective actions, that the establishment can support inadequate lethality was not the root cause, 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 the scientific gaps. And we're not going to go into details on the recommendations to reduce vulnerabilities, but we do want establishments to be aware that there are recommendations in the guideline of things that you can do to reduce your vulnerability, but these are not required.

So, as I mentioned, relative humidity is a critical operational parameter for all cooked products. But FSIS options were originally developed for cooking large mass products like roast beef and smokehouse where cooking is often several hours. So there are some processes that I'll talk about 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 impingement oven may only cook for 10 minutes or less. And for these short cooking options, FSIS's only option is to apply 90% relative humidity for the entire cooking time. However, it's impossible to maintain 90% relative humidity at temperatures above 212 because of the way the relative humidity scale works. There is some research on certain processes, they use dew points percent by moisture volume, or wet bulb, but more research is needed to come up with alternative options for these processes.

FSIS has identified short time, high temperature cooking as a process that can continue to follow the 1999 parameters, meaning monitoring endpoint time and temperature without addressing relative humidity. So this gap can be referenced in the hazard analysis as scientific support for why relative humidity is not addressed in the process. But again, the establishment must still follow the other parameters of time and temperature if following this option. Another such gap are products cooked using microwave cooking methods that are not designed to control relative humidity. So processes that meet this gap include those in which a meter poultry product is cooked using a continuous or non-continuous microwave oven. In these systems, again, it's not possible to follow the relative humidity options of 90% or [inaudible 00:32:00] the oven. So establishments can use this gap of support for using any FSIS time temperature combination without addressing relative humidity.

The next scientific gap are for products cooked using cooking methods that are not designed to control relative humidity other than microwave oven. So processes that meet this gap include those where the product is either cooked in an oven that's not designed to be seal, so there's no dampers, or designed without a mechanism to introduce steam. So many convection ovens are designed with no dampers, no way to be closed, and also no mechanism to introduce steam. Also, within this gap include barbecue products that must be cooked under dry heat to meet labeling requirements. So again, products within this gap, establishments can use this gap of support for using any FSIS 10 temperature table addressing time temperature, but without addressing relative humidity.

Meryl: ...without addressing relative humidity. The next scientific gap are filled meat and poultry products. So these are processes that may inherently maintain relative humidity around the meat and poultry filling but cannot follow one of the relative humidity options. So we know products, such as pasties, in which there's an edible wrapping that fully encloses the raw meat or poultry filling. Relative humidity is not desired in the cooking environment to create browning and the nice, flaky texture of the dough. But while we don't have alternatives at this time, and while we wait for research to be conducted, establishments can use this gap as support for using any of the time, temperature combinations, addressing time and temperature without addressing relative humidity.

The next scientific gap are for processes where the drying step comes before cooking under moist conditions. Products that meet this gap include those in which products are dried to reduce the water activity. And an example would be something like cooked country-cured ham that's been cooked once using one of the following options that ensures high relative humidity. So until more research is conducted, establishments can use this gap to support following any of the time temperature combinations, and then following one of these relative humidity options. And then the last scientific gap involves products with long heating come up times. So I talked about these earlier, and this gap applies to processes such as hand and brisket, that due to their size, require a heating come up time longer than six hours. So it's just not possible to get the product up to temperature between 50 and 130 in six hours or less due to the physical size of the product. So for these products, this gap can be used to support following FSIS with time temperature guidance, addressing all the parameters, including relative humidity, without addressing heating, come up time as a critical operational parameter.

So this table's intended to better explain the scientific gaps I just went through and the list of products I shared at the beginning that are not covered by the guidance. So there are some products where researcher outbreaks demonstrate FSIS guidance is insufficient to result in the safe product. These products cannot use FSIS guidance as scientific support and identify alternative support. An example of this is salt-cured and dry country cured ham cooked multiple times under dry conditions, which was a contributing factor in Listeria [inaudible 00:35:49] outbreak.

There are other products where there's no evidence showing an imminence of safety concern, but current parameters also have not been validated. These products can use FSIS guidance. Again, the 2021 revision includes the 1999 parameters that can be applied. An example here would be salt cured and dry country cured ham cooked once under moist conditions. FSIS guidance was not designed for this process and yet we have no evidence showing an imminent concern. So the guidance can be applied while research is conducted. Finally, for appendix A, the guideline has information on how to handle heating deviations. And we've identified three common types shown on this slide. The guideline has information on how to use pathogen modeling and sampling to determine product of position after deviation.

So to summarize appendix A, FSIS revised its cooking guidance in 2021 in response to public comments. The guidance contains time temperature and relative humidity recommendations for cooking meat and poultry. The guidance specifies those products that are covered, and those that are not. And it also

includes processes that can be used until further research is conducted over the scientific gaps because there's insufficient evidence showing any imminence in safety concern, Establishments that utilize previous versions of appendix A or B of support should either update to the 2021 guideline or identify alternative support by December 4th, 2022.

Now, before getting to the questions, I do just want to share the takeaways we plan to share with our inspection program personnel during their webinars, so that everyone is receiving the same information. So we want to remind IPP that per notice, 59-21, they are to make establishment management aware of the guidelines. We want them to be aware that FSIS will provide further instructions before the December implementation date. And these instructions will be in the form of an FSIS notice describing the verification procedures IPP are to follow in relation to the 2021 guideline, including verification procedures for processes within a defined scientific gap.

And then we want them to be aware that the specific changes from the previous versions are listed in the guideline. We want to be sure IPP are aware that the options in the body of the 2021 guideline, those are those time temperature relative humidity parameter may be used as support by establishments to meet Element 1 of validation, and that the time temperature and relative humidity options 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.

And then we also want them to be aware that establishments using those common cooking procedures that use the 1999 version of appendix A but cannot achieve the relative humidity or heating come up time in the revised guidelines may be able to use the scientific gap as support for not addressing the critical operational parameter. As we discussed, there's a vulnerability with using the scientific gap, but FSIS has determined there is not an imminent public health concern and establishments can use the scientific gap until more research is conducted. IPP [inaudible 00:39:25] establishments that produce products falling into a scientific gap are encouraged to refer questions to their supervisor, or as needed can submit questions to ask FSIS. And Scott is going to share the specific ask FSIS information at the end of the presentation. So with that, I'd like to stop and see if there are questions on appendix A. And we'll start first with the chat. And Laine Zipperer will be reading those. So actually, if first our moderator could give a reminder, please, for how to submit questions to the chat or over the phone.

Speaker 1: Absolutely. So once again, ladies and gentlemen, if you would like to ask a question via WebEx audio, please press the raise hand icon, which is located above the chat box on the right. This will enter you into the question queue. If you are joined via regular audio, please press pound two on your telephone keypad. This will enter you into the question queue as well. Also to submit questions via chat, select all panelists in the chat box, type in your question and send.

Laine:	Hello. Can everyone hear me?
Speaker 1:	Yes, go ahead.
Laine:	Yes. We have four questions in the chat that I would like to read. First question, please clarify which pathogen modeling programs are acceptable for FSIS standpoint. Is it ARS, PMP or [inaudible 00:41:13] or cetera?
Meryl:	Yeah, thank you for that question. So both in appendix A and B, we provide listings of various pathogen modeling programs that are available. And FSIS recommends that establishments rely, if they want to rely on the results of a pathogen modeling program alone, and this could be to support product safety in the event of a deviation or for developing a customized cooling or cooking schedule that the model be validated.
	And there's a number of validated pathogen modeling programs available. The number of those listed in the chat are those related to cooling and assessing the C. perfringens outgrowth. So there's a number from the agricultural research service that have been validated that we list in the guideline and as well as modeling program [inaudible 00:42:08] based. So it really depends on the use. But we did list in both guidelines, which pathogen modeling programs are validated. It is important to be aware that not all programs are validated. Sometimes modeling programs, and there are some also from ARS that have not been validated, but can be used to give just a good initial estimator of growth. So again, it's important just to look for the specific model and look in the guidelines to see if it's been validated. And we can also answer those questions and ask FSIS.
Laine:	Thank you.
Meryl:	If you could read the next question Laine.
Laine:	Yes. Question number two. Page 31 in appendix A states heating meat or poultry products that weigh 10 pounds or more in an oven maintained at 250 degrees Fahrenheit. The question is, is this for the tray 10 pounds or individual meat 10 pounds? We use a commercial electric convection oven and use chicken and turkey gizzards that is frozen about 15 pounds a box. And veal and lamb five pound grounded or cubed. We put two to four patties per tray.
Meryl:	Yes. So for that question, that guidance does refer specifically to the piece of, a roast that's 10 pounds or more. It does not refer to a tray of products that totaling together would equal 15 pounds. And it is important that establishments look at both the size of the product so that each product weighs 10 pounds or more and that is cooked in an oven maintained at 250 degrees or higher. And that's because the research found both of those conditions needed to be met. And it has to do with the ratio between the surface area to the inside of the product. But I would encourage you again, to look at those scientific gaps.

	It may be that the scientific gap related to those other types of cooking systems, such as convection ovens, would apply. And then in that case, that scientific gap can be used as support for not addressing relative humidity. You can also always submit a question through ask FSIS with a specific detail of the type of oven that you're using. And we can also provide guidance about whether it's likely to fit in that gap or not. Next question.
Laine:	Next question. I read that the appendix A applies to small and very small manufacturers. Is that true? And if so, why?
Meryl:	Yeah, so we do discuss this in all of our guidelines that the guidance is focused on small and very small establishments in support of the small business administration's initiative to provide small businesses with assistance under the small business regulatory enforcement fairness act or SBREFA. However we do say all meat and poultry establishments of all sizes may apply the recommendations.
Laine:	Next question.
Meryl:	Next question.
Laine:	Was it mentioned that cooking and casing do not need relative humidity guideline?
Meryl:	Yes. So we do discuss in the 2021 version, how establishments can use cooking a product in a casing, including those that are natural casings, and they can use the guidance of support for not addressing relative humidity. So we talk about how cooking products in casing holds moisture, and that includes natural casings, cellulose casings, collagen casings, fibro and plastic casings. And so that can be found on page 31 of the revised guidance.
Laine:	Next question. What type of rotisserie oven is exempt from RH monitoring?
Meryl:	Yeah. So for that, we talk about the different categories of products that do not need to address relative humidity. So that includes those where relative humidity is inherently maintained. So that would include the casing example we just talked about, but by cooking the product in a casing, the moisture inside is inherently maintained. The other category where relative humidity does not need to be addressed are for products cooked using direct heat. So certain rotisserie ovens do use direct heating in which the heat source is in direct contact with the food. And so this is going to give more of a grill quality. And the key is really that heating is occurring by conduction. And so it will really depend on the type of rotisserie oven and where the heat source is positioned. And again, if there are questions about a specific rotisserie type, we can look at those and ask FSIS.

Laine:	Thank you. For the next question, for smoke heat treated products reaching 144F with no ho time, how does RH apply?
Meryl:	Yeah, so Scott is going to touch on that in appendix B. So, as I mentioned, appendix A is only for products that are cooked to lethality. It does not address partial heat treatment of product. So a product cooked to 145 with no hold time would be considered partially cooked, that would not achieve lethality. But appendix B does cover partially heat treated products, and it addresses the heating come up time, as well as the cooling time. And Scott will talk about how we have a scientific gap for relative humidity supporting it would not need to be addressed. And this is common for products such as bacon, which are smoked and heat treated and not cooked to lethality. So we'll touch on that with appendix B.
Laine:	Thank you. When considering evaporative cooling of surface in dry cooking environment, is the monitoring of surface temperature an option to address this concern?
Meryl:	Yes. So there are some alternatives. There is a surface lethality concept that Dr. Jeff Sindelar at the University of Wisconsin has worked on. And so there are ways to look at monitoring the surface temperature to address surface lethality. And we do discuss it a little bit in the version of appendix A. So FSIS does not have a recommendation in our options, but establishments are not required to follow appendix A and there are ways to address the surface lethality by looking at the surface temperature.
Laine:	Thank you. The next question is what about ovens that have dampers, but are not designed with a mechanism to introduce steam or measure RH?
Meryl:	Yeah, so we do have guidance in the revision about how establishments that are following the field oven option, which is an option that could be followed for a smokehouse oven that has dampers. And we describe the types of documentation that establishments should provide to demonstrate that they're following that option. So it includes meeting the time and temperature of course, and then to show that the ovens are sealed for the recommended amount of time. And how long that will be depends on the endpoint temperature and the cooking time, which we explain.
	And then in addition to showing the amount of time the dampers are sealed, we recommend establishments also show that when the dampers are sealed, relative humidity is maintained. There isn't a specific relative of humidity amount that you would need to meet. The relative humidity does not need to be monitored with each batch or lot. It could be something that's measured during initial validation and ongoing verification. We also provide ways to do that using something like a wet bulb thermometer. And we even have a video about how to make a wet bulb thermometer with really inexpensive material. So we do address those concepts, but you do not need to introduce steam. The

	oven is there, option for sealing the oven is different than the introducing steam options. So I would look at those recommendations.
Laine:	Thank you. The next question, in a smokehouse environment, where we condition to remove excess water, then smoke, then cook to lethality, which portion is considered the cooking time? The entire process, or just the smoke in which we are bringing the product up to the temperature?
Meryl:	Yeah. So we may need to look at that question specifically, but generally we define the cooking time as the time the product is placed in the oven until the time the final time temperature is reached.
Laine:	Okay. We have several more questions. And let me go to the next question. And the remaining questions can be addressed at the end of the presentation. The last question is, can you confirm the relative committee parameters from the 1999 version of appendix A are not required to be used or met for scientific gaps one through four?
Meryl:	Yes, that is correct. So the first four scientific gaps are all related to processes that cannot follow the relative humidity recommendation. For all of those scientific gaps, short term, short time, high temperature, microwave cooking, products cooked in ovens that cannot be sealed or introduced steam and filled meat and poultry products, establishments can cite those scientific gaps as support for only monitoring time and temperature without addressing relative humidity. So let's see if we could just take a few more questions, because I know we want to make sure that there's time that we covered these questions.
Laine:	Sure. All right. The next question is, where smoking is used as conditioning step for product, is the smoking part of the cut, the C-U-T, also would relative community need to be addressed during the smoking time or just the cooking?
Meryl:	Yeah. So again, I think for some of these questions, we need to look at the specifics of the process and can provide that in ask FSIS or was mentioned earlier, an EIO through the district office can provide outreach assistance. But typically yes, the cooking time is considered the time the product is placed in the heated oven until the lethality time temperatures is reach. So that would include the smoking time, anytime the product is between 50 and 130 degrees. And the relative humidity would be included although many of the relative humidity options, if the final time temperature, if the final internal temperature is 145 or higher, the options such as sealing the oven or introducing steam needs to occur over 50% of the cooking time or one hour, whichever is longer. So it's really going to depend on the option, how long the relative humidity option needs to be applied for.
Laine:	Next question. How fully cooked fermented product cover by 2021 appendix A?

Meryl:	Yes. So if a product is cooked to lethality, then that would be a product that's, like cooked in the casing and that would be included. But appendix A does not address where the fermentation is used as part of the lethality treatment with no cooking or a partial heat treatment.
Laine:	Okay. Next question. Would aerobic versus anaerobic conditions considered for come up times for staff and [inaudible 00:55:37] toxins production? If so, wouldn't it be more prudent to measure the surface temperature or just below the surface of the product, like ham or brisket?
Meryl:	Yeah. So we do talk about how for intact products, it may be possible for establishments to monitor the surface temperature for something like the heating come up or the cooling time. The internal temperatures in appendix A such as the 145 for four minutes, those are internal temperatures. But if the product is intact, there may be ways to use the surface temperature. So, that would be something to look at.
Laine:	Thank you. Next question. Any product with casing is exempt from humidity. How about netted product?
Meryl:	Typically netted products are not going to maintain relative humidity in the same way a product that's cooked in a casing wood. But that's something we could always address individually through ask FSIS.
Laine:	Thank you. The next question is the cooking time when product reaches a lethality time slash temperature combination or the whole time of the product is in the oven? To clarify, we have changed the way we produced our smoke chicken slash turkey drumstick to quickly reach lethality and then dry slash smoke cetera. Would the RH requirement only apply during the initial reaching of lethality or during the whole time of the product in the oven?
Meryl:	Yeah. So as a general recommendation, the cooking time is considered to include the time the product is placed into the heated oven until lethality time temperature is reach. So if you're following a relative humidity option such as sealing the oven for 50% of the cooking time or one hour, whichever is longer, that would be that whole time from the time the product is placed into the oven until the lethal time temperature is reach. But it's always good to review details of an individual question and ask FSIS as each process is going to be different. And then the next question was if the event is recorded and yes, the webinar will be recorded and posted on the same event pages where the WebEx information was found.
Laine:	All right. So the next question, if product and casing is exempt, does that also go for completely net cover products avoid of the gaps?
Meryl:	Yeah. So netted products are not typically considered to be cooked in a casing and inherently maintained to inherently maintain relative humidity.

	temperature are met before six hours?
Meryl:	Yeah. So if the lethality temperature is reached within six hours, then that would support that the heating income up time is less than six hours. So with that, I think it'd be a good place, because I want to make sure that we have time to review appendix B. So with that, I'm going to turn it over to Scott's update, but we are keeping all of these questions and we'll get back to them after we cover the appendix B content.
Scott:	Hello everyone. Can you hear me now and see the next slide of the 2021 FSIS Stabilization Guideline?
Speaker 2:	Yes we can.
Scott:	Great. As Meryl said, I'm Scott Updike and I'm a biological scientist with Remus and the office of policy. And now we're going to be talking about the stabilization guideline. I'm going to go through it a little bit more quickly so that we have more time for questions and have more engagement with you guys at the end of the presentation. But one of the key aspects we need to consider when thinking about stabilization is just what is stabilization? And this was a term that FSIS developed so the process of preventing or limiting the growth of spore-forming bacteria, which can produce toxins either in the actual product or can produce toxins in the human intestine after someone eats the product.
	So typically stabilization processes include some type of cooling or hot holding, but you can also stabilize by creating a product with a pH of less than 4.6 before cooling, or you have a product with a water activity below 0.93 before cooling or a variety of other combinations of pH and water activity. So the primary hazard of concern during cooling and hot holding are Clostridium perfringens and Clostridium botulinum. The 2017 version mentioned Bacillus cereus because that's another spore forming bacteria, which can also cause disease in people. However, if a product is controlled so the Clostridium perfringens does not grow extensively, then you will inherently control B cereus. So we have removed some of the discussion of B cereus from the guidelines to reduce confusion.
	One thing that's a little bit helpful is to kind of show you the life cycle of spores versus vegetative cells and how they interact during the cooking and cooling process. Meat and poultry products could become contaminated with Clostridia during the slaughter dressing process. They could also come from cross contamination in the processing environment, or they could come from the spices or herbs that are added to the raw product. This raw product then goes through a lethality process where all the vegetative cells should be killed if you've followed a validated process, but that leaves the spores left. Now during the cooling process, these spores can grow into vegetative cells. And when you think about it, they don't have any competition from other vegetative cells so that you can have increased growth while the product is in that temperature

Next question. Do you need to monitor cut if your cooking time slash

Laine:

danger zone. So the best thing to do is to stabilize these heat treated products as rapidly as possible, and that will prevent the growth of these pathogens.

What you can see in this diagram is if you cool slowly, those spores germinate, and could produce more vegetative cells. If you just have a small deviation, it's possible to re-cook that product and then cool it rapidly and then have a safe product that can be released to consumers. As with cooking, FSIS has performance standards for limiting C perfringens and C botulinum outgrowth. Again, these codified performance standards are requirements in terms of what has to be achieved. However, it doesn't give the means on how you have to achieve this. So for products without performance standards, establishments are still required to support your decision in the hazard analysis. And to support this decision, FSIS recommends that establishments limit outgrowth to the same levels. In other words, allow no multiplication of toxigenic microorganisms, such as CBOT and no more than one log multiplication of C perfringen during the stabilization of fully cooked or partially heat treated product.

And so in 2021 we released the stabilization guideline or revised appendix B. And this was designed to help establishments understand what are the biological hazards, the regulatory requirements associated with safe production of stabilized products, options establishments can use to prevent the growth of spore forming pathogens. And then we've also included just like within appendix A, some scientific gaps for processes that do not have validated research available yet. We also have recommendations for what establishments can do in the event of a cooling deviation. And we also provided additional resources for alternative support as no establishment has to use appendix B as their scientific support.

So again, just like with A, we tried to make it clear which products are covered by the guidelines and which are not. We tried to delineate which cooling options may be used for products with a full lethality, and which may be used with a partially heat treated. We found that that was one area of confusion from some of the previous guidelines. We've added additional cooling options for certain products based on improved pathogen modeling programs. And we've also tried to add additional journal articles for processes...

Scott: ... Also, tried to add additional journal articles for processes like bacon and scrapple to give establishments more choices about what they could use as their scientific support. So let's discuss with Appendix A. We've described three critical operating parameters for cooling processes. Time and temperature are familiar to many people. The third parameter of pre-cooling conditions is a mixture of intrinsic product characteristics such as salt, pH, nitrite, water activity, which affect outgrowth of spore formers. For example, higher salt content or lower water activity can inhibit C. perfringens growth so that you would have additional time to cool that product because the pathogen will grow more slowly. The various cooling options and associated critical operating parameters are provided in Tables 1 and 2, but to help delineate between the fully-cooked products and the partially heat-treated products, Table 1 can only be used for products that have been cooked to a full lethality. We also have some gray shading within these tables to indicate options where critical operating parameters have changed, or are new since 1999, Appendix B. Option 1.4, which was originally provided in FSIS directive 7110.3 has been included in the 2021 guideline.

FSIS Directive 7110.3 has since been canceled, as directives are intended to provide instructions to FSIS personnel, whereas guidelines such as the stabilization guidelines are intended for industry. We've also noted that full lethality can be achieved by following options in the FSIS Cooking Guideline or alternative support. One thing to note is that this includes products that are cooked to fully lethality, but are later reclassified as not ready to eat. So even if a product that's not ready to eat, but it's had that fully lethality, you may use any of these cooling options in Table 1. One question we've gotten several times since the 2021 version has come out is, "What does the chilling must begin within 90 minutes mean?" So the answer is that the intention of Option 1.2 is for chilling to begin when either the 90 minutes is up or the product reaches 120 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. As we mentioned previously, we did develop some new options, 1.5, 1.6 and 1.7.

We had previously published these in askFSIS Q&A and we've now incorporated them into the guideline. Note that Option 1.5 is similar to Option 1.1, but Option 1.5 provides for an additional 30 minutes of cooling time. Using newer modeling programs, FSIS was able to support extending the time product spent between one 30 and 80 by 30 minutes. Option 1.1 was kept in the guideline during the revision, so that establishment's originally following this option would not have to change their parameters or support. An establishment that'd been using Option 1.1 could certainly switch to Option 1.5. The various cooling options and associated critical operating parameters for products which are not cooked to a lethal time temperature combination are provided in Table 2. Note that both options include heating come up time, the amount of time product spends between 50 and 130 as a pre-cooling condition. This is to ensure cumulative growth of C. perfringens is limited to one log or less. You may notice the cooling schedule for Option 2.1 on the slide as 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 S and clostridia 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 of come up time if the product to pre-cooling conditions are met. This was designed in response to some askFSIS questions we received from establishments looking for support for partially heat-treated cured sausages. They had a heating come up time longer than one hour. As mentioned in the previous slides, some of the stabilization options include pre-cooling conditions. These are conditions that must be met in order to support cooling products according to that option. The intent is that these parameters are met pre-cooling, but logistically, some parameters may be monitored at different points. For example, nitrite and ascorbate may be calculated based on ingoing formulated amounts, brine concentration is calculated from the total salt content and total water content, but this can only be obtained by a lab analysis of the cooked and cooled product.

pH must be monitored after cooking prior to cooling, or the establishment must support how the monitoring location represents the pH pre-cooling. We also made some policy clarifications in this guideline. We better clarify that if a product is fully-cooked, but reclassified, so not ready to eat, it can follow any option. We've also clarified that the temperatures referred to in Table 1 and 2 are internal product temperatures. However, establishments may provide support for monitoring surface temperatures of intact products. 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 clarify that if a process incorporates multiple fully fall to rates, multiple full lethality treatment, that is, if the product is cooked, cooled, and then cooked again the establishment needs to assess the growth of clostridia during the cooling steps following each individual lethality treatment, and does not need to assess the cumulative growth over the multiple steps.

We also have added several more journal articles. In particular, I'd like to highlight two of them. One is for Bacon, Taormina and Bartholomew from 2005 and scrapple, Juneja, et al. from 2010, we have found that many establishments were not aware of these articles and they provide some of the best options establishments may use when producing these products. Now briefly, I want to give a summary of some options for bacon, because we've received a lot of questions about cooling these, and so there are several options establishments can follow when 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 by a ready-toeat standard of identity. This slide has an overview of options that establishments can use both for bacon that's partially eat treated or cooked to fully lethality, and I'll go into greater detail on the next slide.

Also, remember that establishments producing bacon must also consider permitted uses of nitrite and ascorbate or erythorbate and natural sources of these ingredients. As we've mentioned, we've received lots of questions about bacon, because there's multiple options in the guideline and it depends on whether the bacon's partially heat-treated or cooked to fully lethality. For partially heat-treated, smoked products such as bacon, establishments can follow the Taormina and Bartholomew article, which allow for a 15-hour cooling time. However, the establishments would need to address the come up time and achieve specific formulations and critical operating parameters found in the paper. 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 smooth and contains a certain amount of nitrite and ascorbate. You'll notice that this is similar to the Taormina and Bartholomew article, although that has some additional formulation parameters. For bacon cooked to lethality, establishments may follow Option 1.3 in Table 1, or Scientific Gap 3 for bacon products that achieve a lethal time temperature combination, but do not apply relative humidity.

Depending upon an establishment's process and product, Scientific Gap 4 for immersion or dry-cured products may also apply. We have tried to provide as many options as possible to meet the different processes that establishments are using. We've also provided some additional clarifications in that we've removed the discussion of the waiver for the option to allow two log growth. We found that that created confusion and establishments were applying those parameters without first applying for the waiver but since we had not received any waiver requests and the information caused confusion, we've removed that guidance, although establishments are still able to request the waiver like this if they so choose. We've also received many questions around using natural sources of nitrite and ascorbate, and we've updated the guidance to include detailed information on their uses. Specifically, as it relates to nitrite from natural sources, these types of products like celery powder are not considered a curing agent, but this is currently a labeling distinction and not a chemical or meat science-based distinction. FSIS intends to conduct rule 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 natural sources of the ascorbate and may be used to meet Option 1.3 for cooling. These antimicrobials are listed in the FSIS directive 7120.1. FSIS recommends that establishments use natural sources of nitrate containing preconverted nitrite, because the quantity of nitrite and these sources is known. When using pre converted nitrite, establishments should request information from their supplier regarding the nitrite level in each lot of product and calculate the amount of natural source needed to achieve the appropriate nitrite concentration for each lot, as it will vary depending upon the lot source, or receive formulation information from your supplier if the concentration is standardized from lot to lot. Please note that natural sources of nitrite cannot be combined with synthetic sources of pure accelerator, such as erythorbate. As with the cooking guideline in Revised Appendix A, we became aware of several types of processes which had been using Appendix B as support, but that were not supported when the agency clarified the guidance's limitations in 2017. Additionally, we were unable to identify any scientific literature to support these products and processes.

FSIS encourages establishments to conduct challenge studies when appropriate. However, we realize it may not be cost-effective for every establishment to do this. Therefore, we have posted research priorities on websites to communicate with these research needs with ARS and other academic researchers, and we're calling these scientific gaps just as within Appendix A and while waiting for the results of this research FSIS is allowing establishments to continue to use these older operating parameters. Again, there's a vulnerability by using these parameters since they've not been validated to achieve the control of these spore- forming pathogens, but researchers do need time to perform these studies. Just as with Appendix A, these processes have vulnerabilities, because they have not been validated to address all hazards of concern. One other thing to recall is that if a deviation occurs for one of these scientific gaps, it's very unlikely that you'll be able to identify adequate support for product safety without performing product testing. A pathogen modeling probably will not work for a deviation for a scientific gap.

In addition, if FSIS or the establishment collects a ready-to-eat product sample that's positive for a pathogen, or the product is implicated in a food safety investigation, we would verify as part of the corrective actions that you can demonstrate that inadequate lethality or stabilization was not the cause of the positive sample or outbreak. But as additional information does become available, we will update the recommendations, or move them into the main body of the guideline. So the first gap is for large mass non-intact products that physically cannot pool quickly enough to follow the revised option. Usually, these products have been following the older parameters and monitoring the product pool from 120 to 55 in six hours or less. The older guidance noted that products that took longer than one hour to cool from 120 to 80 were likely to exceed the performance standard. However, this wasn't clear and it was difficult for these large products to meet. So one of the keys about this is that it takes certain products. It has to be cooked to full lethality, it has to be a non-intact product and due to its size, cannot fool quickly enough.

It can't just be a small product where you've had a deviation, but for these larger products, you can continue to use these older parameters and products under this gap would be cool from 120 to 55 in six hours or less with continuous cooling to 40. Again, this also includes that cooling has to begin within 90 minutes after the cook cycle is complete. The second scientific gap applies to partially heat-treated, smoked products that contain nitrite and ascorbate or erythorbate, but have long come up and cooling times. The '99 version of Appendix B stated that the cooling option for products containing nitrite, that is the 15-hour cooling option, was for ready-to-eat products. After the 2017 version FSIS 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 have long heating come up times along with the 15-hour cooling times, but the original option was not validated for a partially heat-treated product. So products that would meet this gap include, it's partially heat-treated, it's smoked and has sufficient nitrite and erythorbate.

So for these products, you can continue to cool from 130 to 80 in less than five hours, 80 to 40 and less than 10 hours for no more than a total of 15 hours. Note, there is no come up time parameter for this particular. Gap number three applies to smoked bacon cooked without relative humidity. We are aware that bacon processes will often cook to lethality, but reclassify the bacon is not ready to eat in order to use the slower cooling option. We've also 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. So for these processes that where you have a product cooked to a lethal time and temperature, but no relative humidity, it's smoked sufficient nitrite and ascorbate or erythorbate, then they can use that longer cooling time. Again, this particular gap does not have a come up time parameter. The next gap, Gap 4, is for dry cured products that contain nitrate or nitrite and use equilibration time instead of a cure accelerator.

We know from literature that quick cured products require a cure accelerator for nitrite to have a food safety effect and in turn, allow for a slower 15-hour cooling time. We expect that the equilibration time acts similarly, but no research has validated the length of the equilibration time, for example, whether it's two, three or more days in order to achieve this food safety effect. So for this particular gap, it can be a fully or partially heat-treated product. It's either immersion or dry cured. It has sufficient nitrite and nitrate, and it has some type of minimal equilibration time. If you meet those parameters, then it can be cooled using that 15 hour older parameter. Scientific Gap number five is for products to contain nitrite, use equilibration time instead of a cure accelerator, but do not have a brine concentration greater than 6%. After the 2017 version was issued, we 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 billion nitrite, and at least 3.5% brine concentration.

We had removed this older recommendation because validated pathogen modeling programs had indicated that these parameters could result in greater than two logs growth of C. perfringen. This may be because the products do not contain a cure accelerator, but our understanding is that the equilibration time is used by these processors instead. As with Gap 4, there's no research currently available that has validated the length of equilibration time. So again, if a product has any heat treatment, has nitrate or nitrite, a brine concentration of greater than 3.5, but less than 6% and a minimum of equilibration time with two to three days, they can use the Option. 1.4, where cooling occurs over 20 hours. Then the final gap six, applies to scalded awful that cannot cool quickly enough to follow the new option. After we sent out the 2017 version, we learned that establishments were scalding edible offal to temperature, similar to partial heat treatment. However, these establishments could not follow the options for partially heat-treated products now contained in Table 2. We also went and looked and there was no research on the stabilization of scalded offal.

So for this particular gap, any process that in which edible offal is partially heattreated or scalded, the establishments may then chill the product to 45 degrees fahrenheit in less than 24 hours, similar as they would do with the carcass. I want to take a little bit of time to explain the difference between products not covered versus scientific gaps. For a product not covered, you cannot use the FSIS guidance and must identify alternative supports. One example of this is fish of the order siluriformes. None of the research that has gone into developing the stabilization guideline was performed on these type of fish, so those products just don't apply. In contrast, with the scientific gap, the product where we have no evidence of any imminent food safety concerns, and you can use the 2021 version scientific gaps. The example is like the large mass non-intact products that cannot cool to 80 in one hour, but can cool to less than 55 in six hours.

In addition to the various cooling options and scientific gaps, the stabilization guideline also contains information on cooling deviations, specifically the guideline addresses how to use pathogen modeling and sampling to determine product disposition after deviation, as well as how to use sampling and recooking to support product disposition. Then, as I said, it contains how you evaluate the results of accruing deviation after you've done pathogen modeling, and so the guideline includes information about the validated cooling models that are available. All of these models are free and easy to use, although some may require a sign-in in order to log in. If you need help with these models, you may seek assistance from state university extension specialists or HACCP coordinators. We have recently revised our HACCP validation webpage under the section HACCP Coordinators to include an updated list of these contacts. But depending on the amount of predicted growth, establishments may have different options for disposition, and FSIS always recommends establishments perform pathogen modeling to assess the severity of the deviation.

If there's any possibility of C. botulinum multiplication, which in modeling terms means more than 0.3 logs growth, then the product should be destroyed. In other cases, there are some cases where sampling would not be an option, but the guideline provides additional details about these. So in summary, we have revised our stabilization guidelines in 2021. We've included critical operating parameters for hot holding and stabilization, and we've updated recommendations on how to use pathogen modeling for deviations. We've clarified which products are covered by the guidelines and which are not, and then we've also included the Scientific Gap section, which has the older parameters for some common cooling processes. If establishments that use previous versions of Appendix B as support should either update to this guideline or identify alternative support by December 14, 2022. We have also developed some, just like we did for Appendix A, IPP or to refer questions to their supervisors or ask questions as needed to askFSIS.

Establishments for the IPP, the establishments using these common cooling processes that use the 1999 version of Appendix B, but can't achieve the heating come up times for the partial heat-treated products or the cooling time temperatures or pre-cooling conditions, they may be able to use scientific gaps as support. We've also identified that there is a vulnerability with using scientific gaps, but FSIS is determined it's not an imminent public health concern, and that establishments can continue to use these scientific gaps as support until more research is conducted. Again, if IPP have any questions, they can refer them to their supervisors, and per notice 59-21 IPP are to refer questions to their supervisors as needed to the Office of Policy and Program Development to

	askFSIS and select passive deviations and HACCP validations. Establishments can also submit their questions to askFSIS using the same inquiry type. So by putting in deviations and half validations, you'll ensure that it is referred to Merrill or I, or others on our team. With that, I will take any questions.
Michelle:	All right. Once again, ladies and gentlemen, if you would like to ask a question via WebEx Audio, pressing the raise hand icon above the chat panel, enter into the question queue and also pressing #2, if you are joined via regular phone, we'll also enter you into the question queue. We do have some questions in queue on the phone.
Meryl:	Yes, Michelle, if we can start with the phone, thank you.
Michelle:	All right. Very well. Caller, your line is unmuted, you may go ahead. Rashani, your line is unmuted. Do you still have a question?
Rashani:	Yes. I have the questions for the Appendix A. Actually, we are thinking about, this is the critical operating parameters for the relative humidity section, or Option 2. So in this, it says "Relative humidity of the oven is maintained by a sealed oven for at least 50% of the total cooking time or one hour, whichever is longer." My question is, when you think about the relative humidity, is it considered as humidity coming from the product? Can I consider that my first question? The second question, what is the percentage of relative humidity we are thinking about? Is it 25%, 50%, or is it need to be more than that?
Meryl:	Yeah. Thank you for that question. We don't have a percentage of relative humidity we can provide. We did provide a general rule of thumb in our jerky guideline, that's really just to help establishments that are following the field of an option or introducing theme to get a sense of the amount of most relatively humidity that should be present. But we don't have that research where we could give a number that would apply to all cooked products. Instead, we have guidance within Appendix A about the types of documentation establishments should provide if they're following the field of an option. Again, that documentation would be to show that the oven is sealed for 50% of the cooking time or one hour, whichever is longer. That when it is sealed, relative humidity is maintained, but we don't give guidance about what specific percentage the relative humidity needs to be maintained, and again, because we just don't have the research to know what that should be for all types of cooked products that Appendix A applies for.
Rashani:	In this condition, if it is going to be 25%, it should be fine the way you address it, right?
Meryl:	Yeah. What our inspection program personnel will verify is that you have the documentation to show the relative humidity is maintained. They won't be looking for a certain percentage that you're meeting, because that's not in the guidelines that the types of documentation it includes are to show that the

	relative humidity is maintained. What we mean by that is that the humidity is at the same level throughout the cooking process, and that it doesn't have a big drop, so we won't be verifying you're meeting a certain number percentage.
Rashani:	Thank you very much.
Meryl:	Thank you.
Michelle:	All right. We are now moving to the next caller in queue. Monica, your line is unmuted. You may go ahead. Monica, your line is unmuted. Do you still have a question? Monica McLaughlin? All right. I'm going to assume Monica does not have a question.
Monica McLaughl:	No, I do not have a question.
Michelle:	Okay. Thank you, Monica. Moving to the next call in queue. Milton, your line is unmuted. You may go ahead.
Milton:	Yes. I have a question about an operation that performs a slow-smoking process.
Speaker 3:	that performs a slow smoking process on smoked sausage that cannot meet a come up time, but they do meet the erythorbate and nitrite requirements. Would that process fall into the scientific gap in 6/2 on the slides? Hello?
Scott:	Which scientific gap?
Speaker 3:	Hey, I'm losing you.
Meryl:	Yeah. Could you just be a little bit more specific? You mentioned it can't meet the come up time. Can you be more specific and then which scientific gap [inaudible 01:39:57]?
Speaker 3:	Yes, the process I use, the smoking operation is typically done overnight. It's an old timey process and they will not meet a come up time on that. Would that fall under the scientific gap that was listed in the slide 6/2?
Scott:	[inaudible 01:40:28] partially heat treated smoked products?
Speaker 3:	Right.
Scott:	[inaudible 01:40:32].
Speaker 3:	Do what now?
Scott:	It's possible it could. What I would recommend is that you submit an Ask FSIS question with the specific parameters of that individual process and we could

determine whether or not it did, because in order to meet that gap, there's multiple parameters. So I don't want to tell you incorrectly over the phone of whether or not that would fit that gap.

- Speaker 3: All right, thank you.
- Michelle: We are moving to the next question in queue. Marsha, your line is unmuted. You may go ahead. Marsha Stable, your line is unmuted. You may go ahead. All right, Marsha, I'm not sure if you're double muted or not. You should be able to unmute yourself on the WebEx screen, Marsha, if you'll join via the WebEx audio. Marsha, I'll try one more time. I've now unmuted you. Are you able to hear us?
- Marsha Stable: I can hear you. Can you hear me?

Michelle: Perfect. Yes, ma'am. We can hear you. Please go ahead.

- Marsha Stable: Yes. You all mentioned the pathogen modeling programs. Is there one of the programs that you all recommend or that is perhaps preferable to the others?
- Meryl: Yeah. One thing I can say, and this would be for Appendix B for cooling, we do give a number of validated pathogen modeling programs that are available, including several from ARS, although again, it's important to look at the specific name and also ComBase. Any of those that we've listed as validated can be used and relied upon alone. But we have done published research, which has shown that ComBase is the most accurate. So you're going to be getting results that are going to be the most accurate, which can result in saving products that, maybe from another model, such as the agriculture research, you may end up needing to [inaudible 01:43:07] or test, that ComBase may show that it's able to be released as is.

And that's perfectly okay because they're all validated and acceptable to use, but it has been fine to be the most accurate. So we typically recommend for cooling, the solutions start with that. And it's very important to be specific. It's the ComBase Perfringens Predictor. Again, all of these programs have lots of models. It's important to check the name we left in a guideline. Hopefully, that answers your question.

- Marsha Stable: Yes. Yes. Thank you so much.
- Michelle: All right, we are moving to the next question in queue. Adam, your line is unmuted. You may go ahead. Adam, be sure to unmute yourself on your device or on your computer, selecting the unmute button on the screen. Are you there?

Adam: You hear me now?

Michelle:	Perfect. We hear you. Yes, sir. Go ahead.
Adam:	Sorry about that. Yeah, the question is on the scientific gap on large masses. It says greater than four and a half inches or eight pounds. The parameter of four and a half inches is that thickness of the package or the product? Is it the height of the product? Is it the width of the product? How is that determined or what's the determination on the four and a half inches?
Scott:	The determination is if it's in any one direction that comes to that side.
Adam:	And what happens if, instead of a open-air cook product, what about a product that is, say, vacuum packaged and being cooked? Is it the size of any one direction of that package?
Scott:	Well, that's one of the things that this was designed for, the large deli loaves that'll be cooked in bag.
Adam:	Okay.
Scott:	And so, particularly with that, if you think about the deli loaf, that's thicker than four and a half inches.
Adam:	Okay.
Scott:	Then that's the type of product.
Adam:	But it's in any one direction of the four and a half inches, height, thickness, width, length?
Scott:	Well, for example, let's say you have a Slim Jim type product or a snack stick that's longer than four and a half, then that part wouldn't count. So it's the thickness in all those directions of four and a half inches.
Adam:	Okay.
Meryl:	Yeah, we're really trying to get a product that, due to their size, cannot cool quickly enough. Like Scott said, that long skinny product is not going to have trouble cooling in the same way a large-domed injected turkey breast would. And also, that gap does not apply to products that are cooled in a five inch bucket. It's really intended for products that, due to their size, because of the size of the whole muscle cut, cannot cool quickly enough.
Adam:	So is it just whole muscle product or is it, again, say, a five found package of diced meat that's a bulk pack and being cooked and the package is obviously bigger than four inches in length, width or height, does that apply to that as well?

Scott:	We might need to see the specifics, because we've had some questions about after products cook, establishments put it into a bucket to cool it. And so, in that case, it didn't apply even though the bucket was more than eight pounds or larger than four and a half inches. So it'll depend upon the specific process of if it's cooked in the bag that you're talking about and then cooled from that would be different than if it's cooked and then hot packed in a large pack or a large bucket.
Adam:	So how do we determine that?
Scott:	Well, I would recommend that they submit the very specific details about your particular process through Ask FSIS so we can evaluate it.
Adam:	Yeah. Thank you.
Michelle:	All right, it looks like that's it for phone questions at the moment.
Meryl:	Thank you. Laine, could you read the track questions please?
Laine:	Yes, I see there are a few questions in the chat regarding Appendix B. The first question is: For option 1.2, what is the allowed time between 55 to 40 degrees Fahrenheit?
Scott:	On option 1.2?
Laine:	Yes.
Scott:	The time between 55 to 40. Was that the question?
Laine:	Yes.
Scott:	There's no specific time parameter for that. The product just needs to stay in the cooler and continuously chilled down to 40, because as the product gets closer and closer to the temperature of the refrigerator or cooler it's in, the cooling process will slow down. And so, we didn't put any parameter, like it has to be in a certain amount of time, but if an establishment were to take that product out of the cooler before it got down to 40, then that would be a deviation. It needs to stay in there and continue chilling until it gets to 40 in a continuous manner.
Laine:	Thank you. Next question: When is the deadline to be implemented the updated 2021 version of Appendix A and B in our plan?
Meryl:	Yes. As you mentioned, establishments have until December 14th, 2022, to update to the 2021 Guideline or identify alternative support.

Laine:	Thank you. Next question for Appendix B: For partially heat treated product, that is heat treated in coal multiple times, would the establishment need to consider accumulative growth or does the clock start over at any time? Likewise, if the product receives full lethality multiple times, does the clock restart at any time? Thank you.
Scott:	Yes, and these processes are very different from each other. If a product is cooked to lethality multiple times, then you don't have to assess any cumulative growth. However, if you have a part, especially if you've got multiple partial heat treatments, you would need to consider the come up time, any growth during the come up time, any growth during that first cooling, any growth during that next come up time, and additional growth during that final cooling period, and then add all of that growth together. So that requires some more sophisticated modeling, and we have some recommendations for how you would do that modeling within the guideline. But it definitely has to be assessed cumulatively if these have multiple partial heat treatment.
Laine:	Thank you. The next question is: Appendix B discusses that the water activity of 0.93 needs to be achieved prior to cooling. How is this different than the USDA's definition of shelf stability with water activity of 0.91 or less? This is in the 2014 Jersey Compliance Guideline.
Scott:	Because they're looking at two different things. For stabilization, you're ensuring that the spore formers aren't growing. And so, this just means that C. perfringens and C. bot aren't going to grow, which is different than shelf stability because that addresses other pathogens.
Laine:	Thank you. The next question is: When you refer to bacon, is that all species, including poultry and beef?
Scott:	In general, for example, if you had the [inaudible 01:52:32] paper, it was done in a pork product. So in general, FSIS recognizes that if a journal article is in a red meat, like pork, it would apply and generally should apply to any red meat, but may not apply to poultry. However, options within the Stabilization Guideline are not species specific. So if it's in the Stabilization Guideline, Appendix B, any of those cooling parameters would apply to any of the species.
Laine:	Thank you. The next question is: For formulation with required amounts, nitrites and erythorbates, would an establishment need to demonstrate on a batch by batch basis that each lot are formulated to meet these formulation requirements?
Scott:	Depending upon the cooling options, some of the nitrate concentration is a critical operating parameter. And if the establishment sets it up as a critical operating parameter, then it would need to be monitored on a batch to batch basis. However, it is possible for establishments to set up prerequisite programs,

	which could have alternative monitoring frequencies, and that would be a choice the establishment could make.
Laine:	Thank you. The next question is: Why can't Be Natural [inaudible 01:54:10] be used with the synthetic cure accelerator?
Scott:	The regulations that we have for the use of cure accelerators, such as sodium erythorbate, prohibit their use unless the curing agent is used, because natural sources of nitrite are not considered curing agents. You cannot use a synthetic source of a cure accelerator with natural sources of nitrite.
Laine:	Thank you. The next question is: If we achieve full lethality with humidity via Appendix A and then look to smoke to ideal color development, is there a requirement as to what minimum holding temperature should be maintained, such as 130 degrees Fahrenheit?
Scott:	Yes, the Stabilization Guideline has hot holding temperatures, which you can use as your scientific support for after legality process. If you hold the product over 140, you can hold it there indefinitely. However, if you hold it at 130, you may only keep it there for four hours, and if the product drops below 130 for over 30 minutes, you need to continuously cool it or immediately reheat it.
Meryl:	Yeah, all of those are options to look at, and none of them are requirements. So it's really going to depend on your hazard analysis, but a good place to look if you've already achieved lethality then would be Appendix B because of that point, spore formers are going to be primary hazards of concern. So those are great options Scott mentioned in the hot holding section to look at.
Laine:	Thank you. The next question: Is there a pathogen modeling program that is recommended or preferable to others?
Scott:	I think Meryl covered that.
Meryl:	I think that question was answered over the phone. [inaudible 01:56:43].
Laine:	Thank you. The next question is where can guidance be found for fermented products that are not covered under the revised Appendix A?
Meryl:	Yeah, as I mentioned during the presentation, we do have guidance for fermented products that are not cooled. We have a Lebanon bologna guideline that was developed in response to a specific type of product, Lebanon bologna, but we also talk about how it can be applied to other semi-dry fermented products. Those are products that are fermented but not dried. We also have guidance on our FSIS validation webpage, under validation by product, and there's links to journal articles for fermented, salt cured and dried products.

	So where it's available, we include the link to the actual PDF or open access article because FSIS does not have options like we do in Appendix A. There's just so many unique, critical operational parameters for products that do not rely on cooking, such as those that are fermented, salt cured and dried.
Laine:	Thank you. The next question is: You had mentioned for Appendix B that if there are two lethality steps, that the cooling process should be evaluated independently. What if we have a lethality cook step and additional heat treatment that does not reach an internal lethality temperature? Should that be evaluated cumulatively or independently?
Scott:	In that particular case, where you have a lethality step and then the product is cooled, reheated, and then cooled again, you would need to determine the cumulative growth over all three of those stages and ensure it still meets the performance standard. And we have recommendations on how to do that particular kinds of pathogen modeling in the guideline.
Laine:	Thank you. The next question is: Please clarify if standardized celery powder is considered a nitrite or not.
Scott:	Celery powder will contain nitrate. Cultured celery powder will contain nitrite. And if you are using cultured celery powder, along with cherry powder and you know the amounts, then that can be considered an antimicrobial based on the 7120.1. However, natural sources of nitrite are not considered curing agents and natural sources of ascorbate, such as cherry powder, are not considered cure accelerators. And again, as we said earlier, that's a labeling distinction.
Laine:	Thank you. Next question: Scientific gap one makes reference to non intact large mass products. How about intact large mass product that won't cool down in less than one hour from 120 to 55? Will this scientific gap apply?
Scott:	For intact products earlier, in the guideline, we discussed how establishments could monitor using the surface temperature. And if you're measuring the surface temperature for these intact products, even if they're large mass, should still be able to follow the regular cooling options.
Laine:	Thank you. And that is all of the questions from Appendix B in the chat. Would you like me to go over the questions that were left over from Appendix A?
Meryl:	Yes. Thank you, Laine.
Laine:	Sure. The question is: When should we be recording the humidity throughout the cook? At what stage of the cook?
Meryl:	Yeah, again, there are different relative humidity options and they depend on the final internal temperature and the length of the cooking time. For products that are reaching 135 with the appropriate dwell time or higher and have a

	cooking time of one hour or longer, there are additional options to seal the oven or introduce steam for 50% of the cooking time or one hour, whichever is longer. And that 50% of the cooking time, the oven can be sealed throughout the process. So what matters is that the total amount of time the oven is sealed adds up to 50% of the cooking time, or one hour or more. So it doesn't need to be at the beginning. It could be at the end or it could be at various parts, provided it adds up to 50% of the cooking time or one hour, whichever is longer.
	And again, the cooking time is defined as the time the product goes into the oven until the time the lethal time temperature is reached. And I'll just add on to that, because it's related, you had another question asking why is it that the options are for one hour or 50% of the cooking time, whichever is longer? And that is because that is, again, thinking about the history of Appendix A and how it comes from those command and control options for roast beef. That's a large product. It's cooked for a long amount of time and that's what the research was done on. And so, that's what the research led us to do the options that we have. And so, because we know that not all products can follow those options, like the short time high temperature we talked about, that's what led us to the scientific gap.
Laine:	Thank you, Meryl, for addressing both questions. I have one more for the Appendix A. If we packaged host lethality products without vacuum, is it enough to indicate C. perfringens as the pathogens of concern for the cooling process?
Meryl:	Yeah. FSIS does not distinguish between products that are vacuum packaged or not. All products that undergo a heat treatment, either partial lethality or cooked to lethality, should address the potential for C. perfringens or C. botulinum, or generally spore former outgrowth during cooling. And that's because, as Scott discussed in that diagram, once the product is heat treated or cooked, then the spores can germinate and grow during cooling. And we don't distinguish between those hazards in vacuum packaged or not vacuum packaged products. All heat treated and cooked to lethality products should address the potential for spore former outgrowth during cooling.
Laine:	Thank you, Meryl. Those are the questions from the previous presentation that was in the chat. I see that there's an additional question in the chat right now. So let me read that to both of you. Option for maintaining RH during cooking states that RH has to be maintained by a sealed oven. Can I use an automatic damper that maintain humidity throughout the cook, even if the damper is not always closed?
Meryl:	Yeah. Again, I think the guidance in Appendix A is really helpful in terms of the types of documentation establishments should have to show they're following the sealed oven option. There's a list of four types of documentation. I mentioned showing the time temperature is met and then showing the oven is sealed for 50% of the cook time. So it can be done by the automatic dampers, but you still need to show that the total time that the dampers were sealed was for 50% of the cooking time or one hour, whichever is longer. So you just need

to make sure, if it's set on automatic, that you're able to demonstrate that at the end of the process. Laine: Thank you. There's an additional question in the chat: If 180 to 120 cannot be achieved, is there additional support for this in Appendix B? Scott: Yes, there is. If you are unable to meet one of the options in table one, it may be that if you have a large mass non-intact product that you could use scientific gap number one. That particular gap does not have a 120 to 80 cooling time. Instead, it's just a cooling time from 120 to 55 in less than six hours. Laine: Thank you. That is all of the questions in the chat. Mervl: Okay. Yes, and I know we're a little bit over time. We did just want to make sure we got to really quickly give you an update on the scientific gap. Michelle, if you could just give me presenter rights, please, and I'll just real quickly share those updates with you all. Michelle: All right, one moment. Meryl: Thank you. Before we end for today, we just wanted to share with everyone that we have posted research priorities on our website to communicate the scientific gaps we discussed with our Agricultural Research Service and academic researchers. We do have an interagency agreement we're excited to share with ARS to complete several studies, including one to determine the lethality of Listeria monocytogenes and Salmonella in low water activity cured meat products, such as country cured ham, and identifying acceptable lethal treatments for baked goods that contain raw meat and poultry components. As additional data becomes available, we'll update the recommendations for these gaps with the latest scientific support. We did also want to share that, to address the gap that Scott discussed about the challenges with cooling those large mass non-intact products between 120 and 80 in one hour or less, we did conduct a C. perfringens Market Basket Survey. Between May and September, 2021, we conducted a study to assess the levels of C. perfringens in federally inspected, ready to eat large mass, nonintact meat and poultry products sold at retail locations. Samples were collected at retail locations and analyzed by the Food Emergency Response Network, or FERN laboratories. We had a delay and the results were blinded by FSIS to FSIS, but we've now received those results and are analyzing them. They'll be used to determine whether changes are needed to the cooling recommendations in Appendix B for these products, or if a larger, more comprehensive baseline study is needed. And so, we just want to share here the website so that people are aware of the research priorities and where they can be found. And with that, we do have

some time. We want to thank you for your time and attention today. We do

have some time. If there are any additional questions, we can stay on and answer those.

- Michelle: All right, ladies and gentlemen, as a reminder, pressing the raise hand icon above the chat box will enter you into the WebEx audio question queue, and pound two on your telephone keypad will enter you into the question queue if you're dialed in via regular phone. All right, I do not see any additional questions in queue at this time.
- Meryl: Okay, thank you very much, and just for your awareness, we do have another call tomorrow from 9:00 until 11:00 AM. The call and information is different from today, but it can also be found on the events page. It is a repeat or encore of today's presentation. So we'll be covering the same information, but it will give everyone an opportunity to ask questions again. With that, I don't see any other questions in the chat. Again, we'd like to thank everyone for your participation and for all of the wonderful questions.

We do have the Ask FSIS information here, again, the inquiry tab, to get the questions for the best staff would be the half of deviation and half of validation queues so you can submit any follow up questions. And again, the recording from today's event will be available on the events page, as well as the recording from tomorrow's event. Thank you again for participating.

Michelle: That concludes our conference. Thank you for using Event Services. You may now disconnect.