Chris: Welcome and thank you for joining today's Revised Appendix A and B Guidelines Webinar. Before we begin, please ensure you have opened the WebEx chat panel by using the associated icon located at the bottom right of your screen. You may submit written questions throughout the presentation, and these will be addressed during the Q and A. To submit a written question, select all panelists from the dropdown menu in the chat panel, enter your question in the message box provided, and send. And please note that all audio connections are muted at this time until the Q and A portion. If you require technical assistance, please send a chat to the event producer. As a reminder, this conference is being recorded. With that, I'll turn the conference over to FSIS administrator Paul Kiecker. Please go ahead.

Paul Kiecker: All right, good morning, everyone. Welcome to the event. I just wanted to start off by saying that this is something that we understand is a significant change. We're talking about changes to the way that the guidelines are as far as cooking product concerns with that with [inaudible 00:01:19] as far as round tables and different things. They asked if it was possible for us to do that and go through some of the changes and what can be done to address some of those changes. So, that's what this webinar is about. So this is something that was asked for, and we're providing the information here. So make sure that you take advantage of the time today to learn what the changes are and what the expectations are and to ask questions. There's a lot of time that is set aside to address questions and concerns that you have.

So make sure that you bring those up and ask your questions now. Do not wait until the implementation date to find out what the changes are and what the impact is going to be for you. We also have EIO's that are available to come and take a look at specific questions and concerns that you have and see if there's ways to address them. The team today is going to go through a lot of information. So make sure that you're paying attention, that you're devoting the adequate amount of time to this. Again, this is for you to give you a chance to learn what the changes are and also to ask questions that you have that pertain to your individual establishment and processes that are in place. So I want to say thank you for spending your time with us today, and I wish everyone the best moving forward with this. And with that, I'll turn it over to Meryl to start the presentation. Thank you for joining.

Meryl Silverman: Great. Thank you and good morning. So again, today we're going to be presenting on the 2021 Revised Appendix A and B Guidelines. So you just heard your welcome from Paul Kiecker. Next I'm going to be providing an overview of the changes. I'll then be reviewing the 2021 FSIS Cooking Guideline for Revised Appendix A. As you heard, after each section we'll have an open session for questions. I'll then turn it over to Dr. Scott Updike, who'll be talking about the Stabilization Guideline and Revised Appendix B. And then I'll be coming back to the scientific gaps and providing some updates and next steps. And again, my name is Meryl Silverman, and I'm a senior food technologist with the Office of Policy and Program Development.

So with that, we always like to start by giving a very brief overview of the history of the Guidelines, because it really helps to understand how we got to the versions that we have today. Initially, FSIS had prescriptive command and control cooking and cooling regulations that defined how step by step to cook and cool certain products such as roast beef that had historically been associated with outbreaks. When FSIS moved to HACCP, it removed those requirements and instead implemented codified performance standards that set requirements for the amount of reduction or outgrowth allowed, but didn't require particular ways to achieve those standards.

FSIS only implemented performance standards for the same products that historically had had outbreaks. Along with the performance standards, FSIS issued guidelines in appendices to the final rule called Appendix A and B. These provided optional safe harbors taken from the old command and control regulations intended to help establishments producing products under the performance standards to comply. Over time, though, the guidelines became use of support for many more products than originally intended under those performance standards, which led us in 2017 to clarify their use.

And then in 2021, we responded to comments received on those versions with the final versions of Appendix A and B. So in June 2017, FSIS issued revised versions of Appendix A and B. When the guidelines were reissued, we received a number of comments on them that led to a delay in verification. FSIS responded to all the comments in the Federal Register that was issued in December 2021, announcing that 2021 revised and final versions of Appendix A and B. Many comments we received related to common cooking and stabilization processes for which establishments have used Appendix A and B as support, even though these processes couldn't achieve the critical operational parameters in the revised guidelines. And I'm going to talk more about how we responded to these by creating what we're calling scientific gaps.

So this led us to the 2021 revisions that reflect updates in response to comments based 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 utilize previous versions of Appendix A or B as support should either update to the 2021 guidelines or identify alternative support by December 14th, 2022. The time provided includes the time establishments may need to gather new initial implant validation data, should the change in scientific support result in a change to the critical operational parameters being implemented. So, as you heard, we recommend establishments start considering these changes now.

Along with the guidelines, FSIS Notice 59-21 was issued on December 14th. This notice instructs inspection program personnel 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

for EIO's when performing food safety assessments in establishments using Appendix A or B as scientific support. The notice also includes attachments with changes from the previous versions of Appendix A and B. We also indicated FSIS will provide further instructions before the implementation date of December 14th, 2022, and we're also planning on providing webinars with the same information from today to IPP along with this webinar from industry. And this webinar is also being recorded.

So with that, I'd like to start talking about the 2021 Cooking Guideline and Revised Appendix A. Before going into the specifics of the guidance, we wanted to set the stage for why we have the guidelines. And it's to help establishments support their lethality treatment, specifically cooking. So 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 reduces other pathogens and their toxins or toxic metabolites. The most familiar lethality process is cooking, heating the product to kill hazardous bacteria, but other processes like fermentation, salt curing, and drying can be used to reduce the number of salmonella on a product.

The 2021 Cooking Guideline is really intended to support lethalities from cooking and not these other processes. For these other processes, FSIS does have a guideline with food safety lessons from the 2011 Lebanon bologna outbreak. Although it was developed for Lebanon bologna, it can be used for other semi-dry fermented products. We also recently updated our HACCP validation webpage under HACCP validation by product, and there you can find journal articles that could support the lethality treatment for different fermentation, salt curing, and drying processes. In addition to the listing of these support documents, we also included links to electronic journal articles where possible.

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

FSIS has defined and codified the log reduction of salmonella that must be achieved by the lethality treatment to ensure specific products are safe. Products that have these codified performance standards include roast, cooked, and corned beef, cooked uncured meat patties, and cooked poultry products. Other ready-to-eat products not under a codified performance standard still must be processed to ensure no salmonella survives on the finished product. FSIS guidance can be used to ensure salmonella 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 the biological hazards during cooking, meet the codified performance standards, and ensure safe production of ready-to-eat products. The guideline has options establishments can use to achieve lethality of salmonella and other pathogens. It also has a new concept of processes that do not have validated research available, referred to as scientific gaps, and options establishments can use until research is available. It has resources for alternative support because no one is required to follow the Appendix A options. And it also has recommendations for evaluating cooking deviation.

So this slide has a summary of changes in the 2021 Guideline. It specifies those products that are covered by the guidance and those that are not. It 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, although we want to be clear, the options have not changed. It provides more information about situations when relative humidity does not need to be addressed, including that natural casings, products cooked in natural casings, maintain relative humidity. It includes critical operational parameters for the 1999 Guidance for products included in the scientific gap. And I'll talk a lot more about this. And again, it provides more details for evaluating heating deviations.

So, as I mentioned, one thing the guideline does is to address products that are covered, because this was something that was not entirely clear. So specifically, we discussed that the guideline addresses lethality of pathogens, such as salmonella and meat and poultry products, again, by heat treatment or cooking, including for products that are cooked to lethality but classified under a not-ready-to-eat HACCP plan. We also discuss how throughout the document, references to meat and poultry products may be considered inclusive of meat byproducts, meat food products, and poultry food products as defined in 9CFR301.2 and 9CFR381.1, unless otherwise stated. And we added this in response to questions as to whether the guidance could be used as support for cooking products such as liver, and it can.

We wanted to also be very clear on the products that are not covered by the Guidance because again, over the years, we were finding establishments were applying the Guidance to many more products than it was originally intended. And where we could, we provided recommendations for alternative support that can be used. So for example, FSIS Cooking Guidance and Appendix A was validated for meat and poultry products. It was not validated for fish of the order siluriform, or catfish.

However, we do provide reference to FDA's fish guidance, which does have cooking recommendations that can be applied. FSIS Cooking Guidance also does

not apply to the rendering of pork skins into a pellet, which is a very different process than cooking something like a roast. Establishments may use the cooking requirements in 9CFR94.8B4 as support for cooking pork skins into a pellet. 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 for longer dwell times to achieve the same reductions as salmonella.

However, we do indicate the cooking requirements for rendering in 9CFR315.1A can be used as support for the lethality step. Also, we've gotten some questions about hot filling and although rendering lard and tallow cannot 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 the lethality for a process that relies on drying alone, such as something like biltong or for a process where the drying step comes before the cooking step under dry conditions. And so this could be something like country cured ham that is cooked multiple times under dry conditions. Appendix A would not be appropriate support for that process, and this was something that was identified in response to an outbreak where an establishment was cooking salt-cured and dry country cured ham multiple times under dry conditions using Appendix A as support, which was incorrect for that process.

In addition to dried products, as I already mentioned, FSIS Appendix A does not cover fermented, salt-cured, and dried products, but again, we do have a guidance for Lebanon bologna that can be used as support for other semi-dry products. And then we also have those articles on our HACCP validation webpage under HACCP validation by-products, and they're listed for fermented, salt-cured, and dried products.

Finally, Appendix A does not cover partially heat-treated not-ready-to-eat products. We notice some establishments were cooking products to a temperature such as 145 without a dwell time when Appendix A includes a dwell time such as four minutes or higher at that temperature. Appendix A does not contain those parameters. So we've tried to be very clear that it does not cover partially heat-treated not-ready-to-eat products where the time and temperature and other perimeters in the Appendix A are not met, but establishments can use guidance in FSIS's Appendix B, which Scott will talk about, because that includes both the heating come-up time as well as the cooling time for partially cooked not-ready-to-eat products.

So FSIS Appendix A identifies three critical operational parameters to ensure adequately lethality. These include time, temperature, and relative humidity. And when we discuss time and temperature, we're really talking about two different critical operational parameters. We have the internal endpoint temperature and hold time, which is what we're most familiar with. So again, that's that 145 for four minutes, but we also have the heating come-up time. The time product is between 50 and 130 degrees. So more specifically, again, in terms of heating come-up time, this is the time temperature that's used to

monitor the come-up time to ensure staph aureus growth is controlled. The 1999 version of Appendix A mentioned a potential hazard if come-up time was longer than six hours, but didn't clearly describe it as a critical operational parameter. Since the 2017 version clarified the come-up time limit, we've heard 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, such as passage and modeling, but we've also identified a scientific gap. And I'm going to discuss this in 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 cannot follow the new parameters. These are products for which there's no imminent public health concern, but there is also no scientific support we can provide for that specific process.

For these processes, establishments can support the scientific gap as support for their process. So in this case, as support for not addressing the heating come-up time for products such as ham and brisket that are too big physically to meet the recommendation until new research can be conducted. And at the end of this presentation, I'm going to give you some updates on where we are with filling those scientific gaps.

In terms of the internal endpoint temperature and hold times, these have not changed, and they're still contained in a number of tables. We've tried to make it more clear that there are different tables for meat and poultry. And for poultry, there is still the older cooking recommendation to cook to 160 degrees or the newer tables for chicken and turkey that take into account fat. Again, the cooking times and temperatures have not changed. For the poultry time temperature tables, one common question we get is what is an establishment to do if they do not know the fat content of their product, and we recommend using the worst case scenario or have 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 cooking critical limit, critical control point, but still shipped undercooked product. What that indicates is that the monitoring frequency was not sufficient to detect a deviation. So we've added guidance to ensure that cooking procedures are designed to ensure all products in a batch or lot achieve lethality, 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 their monitoring procedures, and we've included several lessons from these recalls, again that were attributed in part to insufficient monitoring procedures.

So that's time and temperature. We also consider relative humidity to be a critical operational parameter, and that's because relative humidity promotes lethality on the product surface in two ways. One, it reduces surface evaporation from the product during heating, a process called evaporative

cooling. And it also keeps the product surface and any pathogens wet, which prevents product drying.

And the process of product drying can increase heat tolerance of pathogens and in particular for salmonella. So we tried to here to illustrate this concept and why it's important to have moisture in the cooking environment. So as we all are familiar with, when we get too hot, we produce sweat. When that sweat evaporates, it cools us down. And that's a process called evaporative cooling. So as the sweat evaporates from our body, it takes heat with it and cools the surface down in the process. So evaporation really equals cooling.

Now consider sweating in a tropical environment where there's high humidity. You feel wet, sticky. The air is 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 down your skin. And the same thing actually happens to meat and poultry cooked in an oven. If the heat is dry, moisture evaporates from the meat, 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's high, the product surface stays hot, and bacteria are killed, which is what we want.

So the first step to using FSIS's Cooking Guideline is to select a time and temperature from one of the tables that matches the product in terms of the species and the targeted reduction. The next step is to choose a relative humidity option. And these relative humidity options are formatted in a new table to help establishments identify the option that matches their process, because it depends on both the endpoint temperature and dwell time and the cooking time, but these options themselves have not changed and they're the same options from the 1999 version of Appendix A.

Both the 1999 and 2017 versions of Appendix A address situations when relative humidity does not need to be addressed. And so what we tried to do is show how these situations fall under two general groups. The first is where the relative humidity's inherently maintained by the cooking conditions. So this could be something such as cook in bag, immersion cooking, or cooking in casings. And again, this includes natural casings.

We've also gotten a lot of questions about the direct heating methods. And so we've tried to clarify that these include where the heat is by conduction. So the heating element is in contact with the food to rapidly heat the surface. We've 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 clarified that all products should address relative humidity regardless of size, unless they fall into one of these two categories, again, inherently maintaining humidity or direct heating. And establishments that cook using one of these methods as support, they do not need to address or monitor relative humidity as part of their process using this guidance.

We also discussed how establishments may support achieving a five log reduction in meat products instead of the six and a half log reduction for products with or without a performance standard, if they can provide additional support. And we discussed that additional support, which includes using source materials that have been tested or treated or conducting a baseline study, but we did remove detailed recommendations regarding conducting a baseline study because establishments interpreted it to apply to all products, including those following the Appendix A table, six and a half log tablem for meat, when such baseline sampling is absolutely not needed, it is only in the case of the alternative support. So we've removed this information because it caused confusion and not many establishments try to support this alternative lethality.

We also addressed [inaudible 00:26:09] ingredients that are added after the meat or poultry product is cooked to lethality. So things like spices that are added after lethality or different vegetables. And so 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 and document any controls and needs to support its decisions about those hazards. Establishments should have letters of guaranteed COA's or other information which could include sampling by the receiving establishment or information about how the ingredients were treated to support the safety. And we addressed cases when a letter of guarantee would not be sufficient to support the safety and when it would, such as supporting the safety of prepackaged ingredients, such as ketchup or mustard.

So I mentioned before that after the 2017 version of the Guidance was issued, we became aware of several types of processes, which had been using Appendix A and B as support, but were not supported when the agency clarified the Guidance's limitation. Additionally, we could not identify scientific support for these processes, and while we encourage establishments to conduct challenge studies, we realize it may not be cost effective for every establishment to conduct an individual challenge study.

So we've posted research priorities on our website to clearly communicate these research needs to ARS, or the Agricultural Research Service and Academic Researchers. We're calling these specific processes with research needs scientific gaps. To share information in a timely manner, we've updated our guidance to address the 2017 comments. And while waiting for the research results, we're allowing establishments to continue to use the 1999 parameters by including them in the 2021 guidance. So establishments using older versions of Appendix A and B still need to update to the newer versions, but they'll find those parameters for these certain processes.

We do recognize there is a vulnerability that these parameters have not invalidated to achieve lethality or for Appendix B control for former growth, but researchers need more time to conduct studies. And these older parameters included in the gaps are intended to be used as scientific support for decisions

in the hazard analysis. And again, at the end of the presentation, I'll give you an update on research being conducted.

There is a vulnerability in following these scientific gaps, but I want to be clear that establishments can use the scientific gaps as support for decisions in their hazard analysis. We just wanted establishments to be aware, though, that these have not been validated for all hazards of concern. And again, the original research used to develop Appendix A and B was for a really limited set of products. So if a process deviation occurs, and this could be something like a power failure for a process that's included in the scientific gap, it's unlikely an establishment would be able to identify adequate support without performing product testing.

Also, if FSIS, or the establishment, collects ready-to-eat samples that's positive for salmonella or the establishment is implicated in a food safety investigation related to salmonella, FSIS would verify as part of the corrective actions that the establishment can support inadequate lethality was not the root cause if they want to continue to use the older recommendation. And then as additional data becomes available, FSIS will change the recommendations for processes that fall under one of these scientific gaps.

So as I mentioned earlier, relative humidity is a critical operational parameter for all cooked products, but FSIS options were originally developed for large mass products that take a long time to cook. For products that are cooked under less than one hour, FSIS only has one relative humidity option, which is to maintain 90% relative humidity. However, for products cooked for short times at high temperatures above 212, it's not physically possible to maintain 90% relative humidity because the way the humidity scale works above 212 degrees. There is some research on certain processes that use dew point, percent moisture dry volume, or [inaudible 00:30:40] to ensure surface lethality.

However, more research is needed to develop an option for these products. So we've identified short-time high-temperature cooking as a process that can continue to follow the 1999 parameters of time and temperature without addressing relative humidity. So again, this gap can be referenced in the hazard analysis as scientific support for-

Meryl Silverman: ... gap can be referenced in the hazard analysis as scientific support for why relative humidity does not need to be addressed for the process. Another scientific gap is microwave cooking. So products cooked using microwave cooking either continuous or non-continuous are these systems are not designed to control relative humidity. So again, for these processes that fit this gap, they can use the 1999 parameters of time and temperature without addressing relative humidity. The next scientific gap includes products cooked using other cooking methods other than microwave ovens that are not designed to control relative humidity. So, processes that meet this gap include products that are cooked in ovens not designed to be sealed. So they have no dampers and also designed without a mechanism to introduce steam. Those can include

some types of convection ovens. Also, it includes barbecue products cooked under dry heat because they're required to be cooked under dry heat to meet labeling requirements. So products in this gap, again can support only following a time-temperature parameters without addressing relative humidity by citing this gap for support for the hazard analysis.

The next gap is for filled meat and poultry products. These processes may inherently maintain relative humidity around the meat and poultry filling, but they can't follow one of the relative humidity options because relative humidity is not desired for browning and crust texture development. And so, for these processes, because we don't have research validating the conditions within the cooking environment products that are used in edible wrapping to enclose the raw meat or poultry filling, including dough, leaves and edible rice paper can use the scientific gap to support monitoring time and temperature without addressing relative humidity until that research can be conducted.

And then this last gap related to relative humidity are for processes where the drying steps comes before cooking, but under moist conditions. So processes that meet this gap include those in which products are dried to reduce the water activity. So thinking about that country cured hand product, but then are cooked using one of the options that ensures high relative humidity. So these are options 1, 3, 4, or cooking-in-bag or immersion cooking. Appendix A was not originally intended for products that were dried to reduce the water activity and yet these relative humidity options we think would ensure surface lethality. So, while research is being conducted, establishments can use any time-temperature guidance addressing all critical operational parameters, including one of these relative humidity options for products that are dried to reduce the water activity. Again, such as country-cured ham.

And then our last scientific gap is for products with long heating come-up-times. And so, this applies to processes such as ham and briskets that due to their physical size take longer than six hours to heat up between 50 and 130. So for these products, they can cite this gap to support using the time-temperature and relative humidity guidance without addressing come-up-time as a critical operational parameter.

So, I do just last want to explain the difference between the scientific gaps I just talked about in the beginning of the presentation where I shared that there are certain products that are not covered by the guidance. So, there are some products where research or outbreaks demonstrate FSIS guidance is insufficient to result in a safe product. These products cannot use FSIS guidance as scientific support and must identify alternative support. An example of this is salt-cured and dried country-cured ham cooked multiple times under dry conditions because this was a contributing factor in an outbreak. But there are other products where there is no evidence showing that imminence in safety concerns, but current parameters also have not been validated. These products can use FSIS guidance. Again, the 2021 revisions that includes the 1999 parameters. An example here would be salt-cured and dried cooked country-

cured ham that's cooked once under those moist conditions. FSIS guidance was not designed for this process, but there's no evidence showing in their concern. So establishments can use the scientific gap until more research is conducted.

Finally, for Appendix A as I mentioned, it includes a lot of information establishments can use to support product safety for three common types of heating deviation. And the guideline has Attachment A2 with information on how to use pathogen modeling, including the validated pathogen modeling programs that are available along with sampling to determine product disposition. So, to summarize for Appendix A, FSIS has revised this cooking guidance in 2021 in response to public comments. The guidance contains time-temperature and relative humidity recommendations for cooking meat and poultry. It specifies those products that are covered by the guidance and those that are not. It also includes older parameters for some common cooking processes that can be used until further research is conducted. Again, those are those scientific gaps because there's insufficient evidence showing an imminent food safety concern. Establishments that utilize previous versions of Appendix A or B as support should either update to the 2021 guideline or identify alternative support by December 14th, 2022.

Now real quickly before getting to questions, we did also want to share with you the takeaways we plan to share with our inspection program personnel so that everyone is hearing the same information. So, we do want to ensure IPP are to be aware that per Notice 59-21, they are to make establishment management aware of the revised guidelines. Again, we will provide further instructions to IPP in an FSIS notice before the December implementation date with verification instructions. And we do want them to be aware that the specific changes from the previous versions are listed on pages 6-8 of the guidelines to help establishments understand how the changes will impact them. We also want to make sure IPP are aware that the options in the body of the guideline that's those time, temperature tables, the relative humidity parameters may be used as support by establishments to meet Element 1 of validation. And also the time, temperature and relative humidity options from the previous versions did not change and are all included in the revision.

And also, that establishments are not required to follow the parameters and may use customized support. And then finally, we want to make sure IPP understands that establishments using common cooking processes that use the 1999 version of Appendix A, but cannot achieve the relative humidity or heating come-up-time may be able to use the scientific gap as support for not addressing those critical operational parameters. There is a vulnerability with using a scientific gap as support, but we have determined that there's not an imminent public health concern and establishments can use these scientific gaps of support until more research is conducted.

So with that, we have time to break and address questions around Appendix A. So, Chris, if you could please remind participants to submit questions through the chat or over the phone.

Chris: As a reminder, if you would like to submit questions via the chat you can do so by sending your chat questions to all panelists. Now, if you are on Webex through the phone line, you can click the hand raise icon at the bottom right of the participants' panel. And if you are only dialed in on your phone, you can press #2.

Speaker 1: Okay. We have three comments coming in from the chat. The first question is, "In regards to no humidity requirements for sausages cooked in natural casings, the guideline also states that the impermeability of the casings depends on the process the establishment uses. So is the establishment required to validate that their process achieves the impermeability of the casings?"

Meryl Silverman: No. So establishments that cook products in natural casings do not need to validate that they inherently maintain moisture. The guidance can be used as support for that, but we do want to be clear that there are some times that establishments, for example, for fermented and dried sausages that are not cooked, the product is intentionally dried to lose moisture. And so, the guidance would not apply in that case, but for cooking products in a natural casing, we've determined that the guidance can be used to support, they inherently maintain moisture and the establishment would not need to validate that.

Speaker 1: Okay. Second comment actually has two questions in it. "Humidity options 1 and 2 do not state a specific humidity level that needs to be achieved. Appendix A cite Mann and Brashears (2007), which supports the need for at least 30% relative humidity during cooking of roast beef. Process humidity affects salmonella lethality at the surface and core of impingement cooked meat and poultry products published in the Journal of Food Protection in 2021 also supports the need for at least 30% relative humidity in whole muscle beef strips, ground beef patties, whole muscle chicken breast fillets, and breaded ground chicken patties. If the body of work that supports a minimum of 30% relative humidity to achieve adequate lethality continues to grow, will FSIS update these options with 30% relative humidity that needs to be achieved? Would a prudent plant work to achieve these levels now?"

Meryl Silverman: Yeah, that's a great question. And I know we've gotten a lot of questions about the two relative humidity options that were mentioned. And so these are for products that are cooked to 145 with appropriate dwell timer higher and cooked for one hour or longer. And in those cases, establishments have options to seal the oven or continually introduce steam for 50% of the cooking time or one hour, whichever is longer. And so for any establishment following those options, I really recommend we look at the guidance. We have a specific listing of support establishments should provide to show they're meeting those options. And you'll notice they do not include meeting any particular relative humidity percentage. So, what establishments should be doing is showing that they're either sealing the oven or introducing steam for the recommended amount of time. And when they do that, they can show that the relative humidity is maintained.

And that means that it stays at a constant level. Again, we don't recommend meeting any particular percentage and that's because we need to be aware that our guidance applies to so many different processes. And so in order to provide one number such as 30%, we need to really be sure that that's the right amount for all the different products and processes that use Appendix A. But we're really excited about all the research that's being conducted that was referenced by the comment and we'll talk about it again. And we definitely do plan to look at that and if we think there's enough information would consider making such a recommendation in the future. Either for all products or specific products.

And definitely for impingement events, we're looking at alternative ways to measure moisture for surface lethality, such as wet bub, dewpoint, moisture by volume, but we just don't have enough information yet as an agency to make one recommendation. So again, at this time, establishments do not need to meet any particular percentage or minimum relative humidity, but they do need to demonstrate the relative humidity is maintained by either the sealed oven or introducing steam. So thank you for that comment.

Speaker 1: And we've had a couple of questions asking if this PowerPoint is going to be made available?

Meryl Silverman: Yeah. So on the event pages for today's event, you can find a PDF already of this presentation that's available, and we'll also be posting the recording.

Speaker 1: And what does the acronym IPP stand for?

Meryl Silverman: Inspection Program Personnel. So those are the inspection program personnel from the office of field operations that are in the establishment conducting the verification activity.

Speaker 1: And the last question in the chat is, "Where can detailed gap information be found?"

Meryl Silverman: Yeah, so we have a table in both guidelines that there's a page for each of the scientific gaps and has detailed information in terms of the types of products that fit under the gap, the parameters that can be applied and some considerations establishments can use to reduce their vulnerability. Those are just recommendations and do not need to be followed [inaudible 00:45:22], just need to follow the critical operational parameters that are listed. So, I encourage everyone to really review those pages to see if your process fits in the gap. And if you're not sure, we have the askFSIS information here and Scott will talk at the end with the inquiry type to make sure that it goes to our office. And so we're happy to review specific details of any process to give some feedback on whether it may fit under a gap.

Speaker 1: Great. We have a couple more questions just came in. "Is there a minimum cook time where the humidity requirements would not apply?"

Meryl Silverman: Yes. So, our relative humidity options depend on the final internal time and temperature as well as the cooking time. So, let me see if I can pull up that table, which would help... So, that's why we've formatted this in this version in a table to better help establish and figure out based on the end point temperature and the cooking time which relative humidity option is available. So, for processes where the cooking time is less than one hour, relative humidity needs to be maintained at 90%. The additional options become available for cooking times one hour or more. And when the end point temperature is 145 with the appropriate dwell times such as four minutes or higher, that's when establishments have the ability to follow either the continuously introducing steam option or the sealed oven option. So, I'd encourage everyone to review this table. We've also included a flow chart to help you figure out, depending on which path you follow, which relative humidity options are available to you.

Speaker 1: Has anyone spoken about the scientific gap process in the new guidelines?

Meryl Silverman: Yes. So everything I shared in this presentation is included in the guidelines. So, there's a background about the scientific gaps, the research priorities, the vulnerabilities. And then again, we have this table which includes each of the scientific gaps on their own page.

Speaker 1: Thank you, Meryl. That is all the questions in the chat.

Meryl Silverman: Okay, great. Chris, do we have any phone questions?

Chris: I do not see any callers in the queue. No.

Speaker 1: We had one more just come in. "Most of the products we cook to 160 and they are cooked in older smoke houses that don't record humidity. How would you recommend to keep records?"

Meryl Silverman: Yeah. So again, we do have a really helpful page and the guideline there's one for the types of documentation establishments should maintain for sealing the oven. And one on the types of documentation establishments should maintain for continuously introducing steam. And the two keys which relate to the critical operational parameters are one, showing for the sealed oven option that the oven is sealed for the recommended amount of time. So again, that's 50% of the cooking time or one hour, whichever's longer. And the cooking time includes the time the product is placed in the oven until the lethal time temperature is reached. So, one is just showing that the dampers are closed for that recommended amount of time. The other is to show that when they are closed, that relative humidity is maintained and that is important for older ovens because it's important to make sure that there's a tight seal, that gaskets are in good repair and that the dampers are really closing.

And so, but that does not mean to be gathered with each batch or lot. So we discussed how establishments could gather data during initial validation and

ongoing verification to show just when the dampers are sealed, there is a tight seal, relative humidity is maintained. We also include a video that we made working with the University of Wisconsin in Madison to show how to make a wet bulb using easy to obtain inexpensive materials. And so, a wet bulb thermometer can be used to calculate the relative humidity when you know the wet bulb and the dry bulb. So that's another resource if you don't have a way to measure relative humidity.

Speaker 1: And there is one caller in the queue.

Chris: Yep. We did have a caller in the queue, but it seems like the caller put down their hand.

Speaker 1: Okay.

Meryl Silverman: Okay-

Speaker 1: Next.

Meryl Silverman: ... I see one more question.

Speaker 1: Yep. We have two more. "How will the research on surface lethality, Sindelar, Glass, and Hanson be implemented into Appendix A?

Meryl Silverman: Yeah. So, with all of the scientific gaps, and again, we'll talk about at the end some of the progress that we're seeing, both with the agricultural research, as well as USDA funded research, such as that being done at the University of Wisconsin-Madison and Michigan State. And so we're really looking at that research and as the results are published, we'll look at whether we can remove the scientific gaps and instead in their place provide alternative options that establishments can provide. So, we're really looking at within the next year, the results of those research and how we can incorporate that into validated options in Appendix A that establishments can use.

Speaker 1: Next question, "Vacuum tumbled, bagged, and sealed products that are then cooked to an internal temperature above 190 degrees, then cooled without being post-lethality exposed can most times be large mass items. For example, a tumbled inside round weighing over eight pounds. This process does not seem to be addressed in the cooling guideline and I would please like some clarification."

Meryl Silverman: Okay. Well, Scott will be covering the different scientific gaps in the cooling guideline, so we can come back to that question at the end. And if it's not answered, then we'll address that.

Speaker 1: Thank you. And our last question, "If the cooking time is less than an hour, but the establishment maintains humidity for one hour, is that acceptable? The

establishment cooked to the appropriate temperature time, this refers to a jerky plant that measures internal temperature."

Meryl Silverman: Yeah. So, the only relative humidity options that are available for products cooked for less than one hour is to achieve 90% relative humidity. And I would encourage any establishment producing jerky to also review our jerky guideline. It was issued in 2014. So FSIS has been very clear even before that time of the importance of relative humidity for jerky products because of the number of salmonella outbreaks associated with jerky that have been attributed to cooking jerky under dry condition. So, it is really important for jerky that establishments follow one of the relative humidity options. And again, for products cooked for less than one hour, the only option that we have available is 90%. And so, if there's more questions about that particular process and what other options may be available, please submit a question to askFSIS and we can provide further guidance.

Speaker 1: No more questions in the chat.

Meryl Silverman: Okay, great. So with that, I'll turn it over to Dr. Scott uptake also from the Office of Policy and Program Development. And again, we'll have time for questions after he presents on Appendix B.

Paul Kiecker: Great, thank you, Meryl. My name is Scott Updike and I'm a biological scientist with the Office of Policy and Program Development. And next, we're going to talk about the 2021 Stabilization Guideline and Revised Appendix B. So, before we begin with this, I want to go and set this stage for why we have this guideline and also discuss what stabilization is because stabilization was defined by FSIS as the process of preventing or limiting the growth of spore-forming bacteria capable of producing toxins either in the product itself or in human intestines after someone eats the product. Stabilization processes typically include cooling and hot-holding. However, there are other ways a product could be stabilized. Establishments may support drying and fermentation, or acidification as stabilization processes. For example, if the product has a pH of less than 4.6 before cooling, or if the product has water activity less than 0.93 before cooling, or there's other journal articles with other mixtures of pH and water activity that have been validated that can also be used to stabilize the product.

And so when we think about stabilization, it's important to understand what the primary hazards of concerns are. And from FSIS standpoint, the two major concerns are clostridium perfringens and clostridium botulinum. Some of you will notice that in the 2017 version, we also discussed bacillus cereus as it is another spore-forming bacteria that could be a hazard of concern during cooling and hot-holding. We have removed much of this discussion in the revision because FSIS does not expect establishments to have additional support from bacillus cereus controls in their hazard analysis if they've already supported control of C. perfringens. In normal operating conditions if C. perfringens is controlled, the bacillus cereus is not a concern. What you do need to be aware of though is in extreme cooling deviations, it is possible for bacillus cereus to

grow to high levels. And then under those situations, it should be considered during product dispositions determinations.

This is a slide that kind of help you understand what's going on in a meat product as it goes through cooking and cooling. To begin with, if you look at the raw product in red, you'll notice that it has both spores and vegetative cells. Meat and poultry products may become contaminated with clostridia during the slaughter and dressing process, or they could come from cross-contamination in the processing environment if any sanitary conditions are present. Another source of these pathogens are spices in herbs can contribute to this spore count as well. And so, during the cooking process, the vegetative cells will be killed, but that will leave only the spores surviving. These spores can grow into vegetative cells during cooling because they don't have competition from other bacteria and the temperature is in the danger zone for their growth. Therefore, the best control to stabilize heat-treated products is to rapidly cool them to reduce the amount of time spores can grow into cells.

One thing to note from this diagram, if the product after it's been cooled slowly, then those spores have time to germinate and the pathogens can grow. And if it grows more than one log of C. perfringens, that's a potential hazard that could lead to illness in people who eat the food. And while later on the guideline will discuss how you would make a determination of whether you can recook a food or what needs to be done. If there is low levels of excessive C. Perfringens' growth, it is possible to recook that product kill off the vegetative cells and then cool it rapidly. And then that product would be safe to release to commerce.

The 2017 guideline also clarified that products which are heat-treated, but not cooked to lethality need to consider the heating come-up-time in addition to the cooling schedule to limits spore former growth. Heating steps like smoking can support the growth of spore formers, but if the product does not reach lethal temperatures to kills the vegetative cells, the pathogen can continue to grow to higher levels during cooling as well. This also applies to products which may be cooked to lethality, cooled, then heated again to sublethal temperatures for browning or double smoking. As with cooking, FSIS has performance standards for limiting C. perfringens and C. botulinum outgrowth in certain products. Again, codified performance standards are requirements and terms of what is to be achieved, not the means on how to achieve that. For products without a performance standard, establishments are still required to support decisions in their hazard analysis. To support decisions in the hazard analysis, FSIS recommends establishments limit outgrowth to the sustained level. In other words, allow no multiplication of toxigenic microorganisms such as C. botulinum and allow no more than one log multiplication of C. perfringens during stabilization of fully cooked or partially heat-treated product.

So, the 2021 Stabilization Guideline is designed to help establishments understand several things. One which you've already gone over is what are the biological hazards during stabilization? Two, the regulatory requirements associated with the safe production of stabilized heat-treated and partially heat-

treated products. Three, various options establishments can use to prevent the growth of C. perfringens and other spore-forming pathogens or processes that do not have validated research available, which we are calling scientific gaps. And then options that establishments can use until the research is available for these processes.

We also give recommendations on how cooling deviations can be evaluated, including recommendations on pathogen modeling and disposition of product based on results. And we also give a variety of resources for alternative support because no establishment has to use the options in Appendix B. These are completely voluntary. In the 2021 Guideline, we listed a summary of all the changes to make it easier for you to understand what has changed between the 2021 and the 2017 Guidelines. So we've specified those products that are covered by the guidance and those that are not. We have clearly delineated which cooling options may be used for products with the full lethality and also which options can be used for those that are partially heat-treated. And we've also made it clear that the products that have received a full lethality, but are reclassified as not ready to eat, may still use those cooling options for-

Paul Kiecker: Not ready-to-eat, may still use those cooling options for a full lethality product. We've added additional cooling options for certain formulated products. We've added journal articles for things like bacon and scrapple. We've also included the critical operating parameters for the scientific gaps for those processes, where there is no research to validate them. And we've also improved the evaluation of cooling deviation to give establishments a better understanding of what they need to do to make a product disposition. And so just like within cooking, it's important to understand what are the actual critical operating parameters for cooling. And so FSIS has described three types of critical operating parameters for the cooling process. Climate temperature are familiar to most people. The third parameter of pre-cooling conditions is a mixture of intrinsic product characteristics, such as salt, pH, nitrite, water activity, which can affect the outgrowth of spore formers. For example, higher salt content or lower water activity can inhibit C. perfringens growth. So if one of the cooling options has these types of pre-cooling conditions, it is a critical operating parameter for that particular option.

But the various cooling options and associated critical operating parameters are provided in tables one and two. We have tried to make it very clear, which is for the full lethality products and which is for partially heat treated. So the options are in separate tables. So for table one, these are options that can be used for products that have been cooked to full lethality, whether they are ready-to-eat or not ready-to-eat. I'm sure some of you have noticed the gray shadings within these tables and that indicates options where critical operating parameters have changed or are new since the original 1999, appendix B. Option 1.4, which was originally provided an FSIS as Directive 7110.3 has been included in this guideline. However, FSIS's Directive 7110.3 itself has since been canceled as directives are intended to provide instructions to FSIS personnel. Whereas

option 1.4 is guidance to industry. So we wanted to make sure it was in industry guidance.

We have also noted in the guideline that full lethality can be achieved by following the options in the FSIS Cooking Guideline and revised appendix A or from alternative support. Full lethality doesn't have to just be achieved by using appendix A, this includes, like I said, products that are full lethality, but reclassified as not ready-to-eat. That was something that had caused some confusion in the previous versions. But if appendix A is used, establishments must address all critical operating parameters, including relative humidity or provide justification. One question that we have gotten multiple times since the revision was issued is whether option 1.2 chilling could begin within 90 minutes, regardless of the temperature at the end of the 90 minutes. And the answer is no. The intention of option 1.2 is for chilling to begin when either the 90 minutes is up or the product reaches 120 degrees Fahrenheit.

Once that product reaches 120 degrees Fahrenheit, there's only one hour to get it down to 80. And that doesn't matter if it reaches 120, 30 minutes after the cook cycle is complete, 60 minutes after the cook cycle that was complete, or 90 minutes after the cook cycle is complete. So that one 20 to 80 is a one hour limit. This option has not changed. And the establishment always had the document when the product reached 120 Fahrenheit in order to demonstrate that the time component was met. As mentioned previously options, 1.5, 1.6 and 1.7 are new cooling options for products cooked to full lethality. These options were available in a public Ask FSIS Q&A, and are now incorporated into the 2021 Guideline. Establishments can use the Stabilization Guideline as support for cooling products according to these options. One thing to note is that option 1.5 is similar to option 1.1.

However, option 1.5 provides for an additional 30 minutes of cooling time using newer modeling programs. We were able to support extending the time the product spent between 130 and 80 by 30 minutes. Option 1.1 was kept in the guideline during the revision. So that established events originally following this option would not have to change their parameters or support. An establishment that has been using option. 1.1 could certainly switch to option 1.5. But one thing to note is in the, is that in the event of a deviation option, 1.1 would still give a chance of using pathogen modeling to determine product disposition. If there's a deviation using option 1.5, it's very likely that more than one log C. perfringens will grow. The various options and associated critical operating parameters for products which are not hooked to a lethal time, temperature combination are provided in table two note that both options include heating come up time.

The amount of time product spends between 50 and 130 degrees Fahrenheit as a pre-cooling condition. This is because there you have to consider the cumulative growth of C. perfringens both during the come up time and the cooling time, since there is no lethality step. And the cumulative growth during both of these has to be one log or less. You may notice the cooling schedule for

option 2.1 on the slide is the same as option 1.1 for fully cooked products. Except for the addition of a one hour, come up time limit. This limit is included to address the potential for growth of staph aureus and 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 a three hour come up time. If the product pre-cooling conditions are met. This option was designed in response to individual Ask FSIS Questions we received from establishments, looking for support for partially heat-treated cured sausage that had a heating come up time longer than one hour.

And that's 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 the options. 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 or erythorbate levels may be calculated based on the ingoing formulated amount. Brine concentration is calculated from the total salt content and total water content values that can only be obtained by a lab analysis of the cooked and cooled product. We would not expect the brine concentration to change after it is cooled and logistically it's not possible to send in a sample pre-cooling.

pH must be monitored after cooking prior to cooling, or the establishment must support how the monitoring location represents the pH pre-cooling. Just to note that I'm using the terms monitoring, but it would be up to the establishment, determine how to incorporate these parameters into the HACCP system, either through a prerequisite program, CCP, or during the initial setup of their system with ongoing verification. And these concepts are described at FSIS HACCP validation guidance.

In addition, the 2021 has a variety of policy clarification. One, we have better clarified that products that are fully cooked, but reclassified to be not ready-to-eat, can follow any option. We have clarified that temperatures referred to in tables one and two are internal product temperatures. However, establishments may provide support for monitoring surface temperature of intact products, such as a beef brisket or picnic shoulder that is not injected or vacuum tumbled. Products should still be cooled continuously. This is important because if the product is removed from the cooling medium, based on the surface temperature, the internal temperature could still be high.

And if it's removed that warm reservoir of temperature may cause a whole product to warm up. We also clarified that if the process incorporates multiple full lethality treatments, such as by the Picking Guideline or other support, the establishment needs to assess the growth of Clostridia during the cooling step, following each individual lethality treatment and does not need to assess any cumulative growth. This isn't a change. Rather we realize through Ask FSIS Questions that the language in the 2017 version was confusing. So the language in the 2021 guidelines better reflects what we had always intended.

I do want to take a moment to highlight two journal articles that we have included in the guidelines that may help establishments support cooling of partially cooked heat, treated bacon and cooling of scrapple products. The Taormina and Bartholomew article was included in the 2017 version of the guideline, but many establishments were not aware of it. And through Ask FSIS Questions we've found that this has been very helpful to many establishments to use as their scientific support for the production of bacon. And speaking of bacon, we have received a lot of questions about how establishments should support their cooling of bacon product. So I'm going to take a moment to highlight several specific options. There are several ways establishments can follow these options when cooling bacon. However, whether one is appropriate or not, will depend on whether the bacon is partially heat-treated or cooked to a lethality.

While a product may be cooked to lethality establishments may reclassify the product as not ready-to-eat, provided the product is not required to be ready-to-eat by a standard of identity. This slide has an overview of the options that can be used for both bacon that's partially heat-treated and bacon is cooked to a full lethality on the next slide. I'll go into greater detail on what those options include. But please note that establishments producing bacon must also consider permitted uses for nitrite and ascorbate or erythorbate and natural sources. These ingredients as described in FSIS Directive 7120.1.

So again, as I said, we've received a lot of questions about this because we have tried to provide as many options for establishments to use as possible. And so just having many options does create a little bit more confusion. So for partially heat-treated, smoked products, such as bacon establishments can follow the Taormina and Bartholomew article, which allows for a 15-hour cooling time. However, the establishments would need to address the come up time and certain other specific formulation, critical operating parameters that were described in that particular journal article. Appendix B also has a scientific gap that allows for a 15 hour cooling time with no heating come up time parameter provided the product is smoked and contains a certain amount of 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 one or scientific gap for bacon products that achieve lethal time temperature combination, but do not apply relative humidity during the lethality process. In addition, establishments may be able to use scientific gas number four, if the bacon was produced using immersion curing or dry curing. Boost does provide a lot of options for establishments. And hopefully one of their processes will be similar to one of these options.

So to continue on with some of the policy clarifications, we have removed the discussion of a waiver option for using a cooling process that allows up to 2-log growth. We found that some establishments were applying the 2-log options

without submitting a waiver. And since 2017, no establishment has submitted a waiver request for this.

So we found it created more confusion than helped. So that has been removed, but establishments can still submit a waiver if they choose to do so. We've also received many questions about using natural sources of nitrite and we've updated the guidance to include detailed information on their use. Specifically, as regarding natural sources of nitrite, we have clarified that natural sources of nitrite, like celery powder, are not considered a curing agent. But this is currently a labeling distinction. It's not a chemical difference. FSIS intends to conduct rule making on these requirements as we've been petitioned on this issue. But in the meantime, it's still not considered a curing agent. Some sources of cultured celery powder are considered as antimicrobial along with the natural source of ascorbate and may be used to meet option 1.3. These antimicrobials are listed in FSIS Directive 7120.1.

FSIS recommends that establishments use natural sources of nitrite containing pre-converted nitrite. Because the quantity of nitrite, these sources is known. When using pre-converted nitrite, establishments should request the information from the supplier about how much nitrite is in each lot of product or receive formulation information from the supplier. If the concentration is standardized from lot to lot, please note that natural sources of nitrite cannot currently be combined with synthetic forms of ascorbate or erythorbate because erythorbate is a cure accelerator. And under FSIS regulation, the cure accelerator can only be used if a curing agent is present. Since natural sources of nitrite are not curing agents, you cannot add a cure accelerator with them. You would have to use a natural source of ascorbate as with the cooking guideline and revise appendix A. FSIS became aware of several types of processes, which had been using appendix B support, but they were not supported when the agency clarified the guidance in 2017.

Additionally, the agency could not identify any scientific literature to support certain products and processes. We encourage establishments to conduct challenge studies when appropriate. However, we do realize it's not cost effective for every establishment to conduct individual challenge study. Therefore we have put many research priorities on our website and has communicated these needs to ARS researchers and academia. And as Merrill mentioned in the appendix A, we're calling these specific processes in need of research scientific gaps. And so while we're waiting for this research to be produced, we are allowing establishments to use the older, critical operating parameters that were present in the 1999 version. There is a vulnerability that these parameters have not been validated to achieve the full controls spore forming growth. But until that's done, establishments may use them as their scientific support.

So I wanted to spend a little bit of time discussing the vulnerability. These processes have not been validated to address all hazards of concern. Another aspect is if a process deviation occurs when you're using one of these scientific

gaps as your scientific support, it's unlikely that you'll be able to find support for the product disposition without performing product testing. If we find out that a outbreak or illness was a result from one of your products that was supported using one of the scientific gaps, the establishment would then have to demonstrate that the stabilization was not the root cause of the illness or outbreak. Which you would need to do if you wanted to continue to use these older recommendations as your scientific support.

But as additional data becomes available, we will change these recommendations either by eliminating them or including them in the main body of the guidelines. We're not going to go into details on all the recommendations to address the vulnerabilities in this presentation, but we encourage establishments who are using the scientific gaps as their scientific support, to read through and consider the recommendations to reduce the vulnerabilities. And if you choose to, you may implement some of the recommendations, but that's voluntary. They're not considered critical operating parameters.

The first gap in the stabilization guideline applies to large mass non-intact products that cannot cool quickly enough to follow the revised option. In general, these products have been following the older parameters and monitoring that the product was cooled from 120 to 55 and six hours are less. The older guidance noted that products could take longer than one hour of cool from 120 to 80 were likely to exceed the performance standard. However, this parameter was not clear and it's difficult to meet for these large products. So if a product is took to full lethality, it is non intact and due to its size cannot cool quickly enough from 120 to 80, the establishment can continue to follow these parameters when chilling within 90 minutes after the cook cycle is complete. These products would be cooled from 120 to 55 in 6 hours or less with continuous cooling to 40.

The second gap is for partially heat-treated, smoked products that contain nitrite and ascorbate, but have long come up in cooling times. The 99 version of appendix space stated that the cooling options for products containing nitrite says 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 with 15 hour cooling times, but that original option was not validated for a partially heat-treated product. So we are creating this scientific gap that establishments can use it as their support. If they're producing partially heat-treated, smoked products that have sufficient nitrite and ascorbate or erythorbate. And so for these products, establishments can continue to follow the older parameters, where it's cooled in 15 hours. There's no come up time parameter for this particular gap.

The third gap applies to smoke bacon cooked without relative humidity. FSIS is aware that bacon processors will often cook to a lethal time-temperature combination, but reclassify, the bacon is not ready-to-eat in order to use the

slower cooling option. Exercise is 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 until that research is conducted establishments that have processes that show the product is cooked to a lethal time and temperature, but relative humidity is not addressed is smoked and is has sufficient nitrite and erythorbate may use this gap. And if they do, they make it cool with that 15 hour total time. And again, there's no come up time parameter for this particular gap.

The fourth gap applies to dry cured products or immersion cured products that contain nitrate or nitrite and use equilibration time instead of a pure accelerator. We know from literature that quick cured products require a cure accelerator for nitrite to have a food safety effect. And in turn are allowed to have that 15 hour cooling time. We expect that equilibration time acts similarly. But no research has validated the length of equilibration time necessary. Is it two days, three days or more? We're not certain. And until that research is done, we are allowing this particular scientific gap for fully or partially heat treated products that have been immersion or dry cured. They have sufficient nitrate and nitrite for the gap, and they have a minimal equilibration time. And again, if you do this, you would have that 15 hours of total cooling time.

The fifth gap applies to product to contain nitrite and use a collaboration time instead of a cure accelerator, but do not have a brine concentration greater than 6%. After the 2017 version of the guidance was issued, FSIS 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 with sufficient nitrite and at least 3.5% concentration. We removed this older recommendation because validated pathogen modeling programs had indicated these parameters could result in more than 2-logged growth of C. perfringens. However, this may be because the products do not contain a cure accelerator, but our understanding is that equilibration time is used by these processors instead. As with gap four, there's no research currently available that has validated the length of equilibration time. So the processes that meet this gap include any heat treatment pumped with nitrite or nitrate, brine equilibration time greater than 3.5% and less than 6% and a minimal equilibration time.

The final gap in the Stabilization Guideline is for scalded offal that cannot cool quickly enough to follow any of the new parameters. After the 2017 revision, we learned that establishments were scalding edible offal to temperatures, similar to a partial heat treatment. However, the establishments could not meet any of the cooling options that were now contained in table two. We also discussed with academia and ARS researchers and were unable to find any research on cooling of scalded offal. So in the meantime, if your process scalds offal, so that it's partially heat-treated. You can cool it as if it's part of a carcass and so it would need to be chilled to 45 degrees in less than 24 hours.

One of the important things is the difference between a product that is not covered versus the scientific gap. So for example, fish of the order siluriform is a

product that's not covered because none of the research that went into developing the parameters or the scientific gaps has been done on fish. And contrast for product with this in the scientific gap, it's a product that's been using the parameters in appendix B for a long time, but we have no evidence showing that there's any imminent food safety concern. It's just that the current parameters can't be applied. So what establishments can do is continue to use the older parameters for these products, such as large mass non-intact products that can't cool quickly enough to 80 degrees.

As I mentioned previously, the Stabilization Guideline contains information on cooling deviations, specifically the guideline addresses how to use pathogen modeling and sampling to determine product disposition after deviations, as well as how to use sampling and recooking to support product disposition. The guideline also contains information on how you would evaluate the results of a cooling deviation after you've used pathogen modeling when the product is still under establishment control. The guideline includes information about the validating cooling models that are available online. All of the models we recommended are free and easy to access. Although some of them may require a sign up for login. Establishments that need help with using these models may seek assistance from State University Extension Specialists or the Asset Coordinators. And FSIS has recently revised its asset validation information webpage under the section HACCP Coordinators to include an updated listing of contact.

Depending on the amount of predicted growth establishments may have different options for disposition. We always recommend establishments perform pathogen modeling to assess the severity of a deviation. As noted on this slide, if there's any possibility of C. Botulinum multiplication, which in modeling terms means a greater than 0.3 log growth, then the product should be destroyed. In other cases, there are some cases where sampling would not be an option. The guideline provides additional detail on each of these options. We recommend that this guideline be reviewed each time as a deviation.

So to summarize, FSIS has revised the Stabilization Guideline and Cooking Guideline in 2021 in response to public comments. Just as with the Cooking Guideline, the Stabilization Guidelines specifies products that are covered by it and those that are not. It also includes older parameters for some common cooling processes that can be used until further research is conducted under the scientific gaps. Establishments have until December 14th to either update to the 2021 version or identify alternative support. Also reminder additional instructions will be provided to FSIS personnel prior to December 14th, 2022. Again, before we get to questions.

Paul Kiecker: Again, before we get to questions, just like we did with Appendix A, I want to share what FSIS is going to tell the IPP so that everyone is on the same page with this. And we want to be sure IPP are aware that the options and the body of this 2021 guideline, the time, temperature, and pre-cooling conditions, may be used as support by establishments producing products cooked to lethality

and heat-treated products to meet Element 1 of validation, to support their hazard analysis decisions.

Cooling options from previous versions of the guideline, 1999 and 2017, and the canceled Directive 7110.3 are included in the revision if they are part of the scientific gap.

Cooling options for ready-to-eat and not ready-to-eat products subjected to a full lethality during production are included in Table 1 of the guidelines. Cooling options for partially cooked products are included in Table 2 of the guide.

Establishments are not required to follow any of the parameters in Appendix B and may use the customized process or alternative support.

Establishments using common cooling processes that used the 1999 version of Appendix B but can not be achieved during the heating come-up-time for partially heat-treated products, cooling time-temperature or pre-cooling conditions in the revised guidelines may be able to use a scientific gap as support for not addressing the critical operating parameter.

But again, we're going to stress to IPP that this could be a vulnerability and that we have recommended ways establishments could address the vulnerabilities, but that those recommendations are voluntary and no establishment using a scientific gap as their support has to follow any of those recommendations for reducing vulnerabilities. They only have to follow the critical operating parameters of the scientific gap.

And as Meryl indicated for Appendix A, IPP are to refer questions to their supervisor or ask questions as needed to askFSIS. And Per Notice 59-21, IPP are to refer questions or to OPPD. And when they do so, they should select the HACCP Deviations and HACCP Validation as inquiry type. And we recommend that establishments use the same inquiry type if they have any questions, because when you choose that it will come directly to the OPPD team that's been working on Appendix A and B, and we can directly address your question.

And with that, we'll take any of the questions in chat or on the phone, or Appendix B.

Speaker 1: Okay. To start with our question from the last chat box... Vacuum tumbled, bagged and sealed products that are then cooked to an internal temperature above 190 degrees, then cooled without being post lethality exposed, can most times be large mass items. For example, a tumbled inside round weighing over eight pounds. This process does not seem to be addressed in the cooling guideline, and we would prefer some clarification.

Paul Kiecker: That would be addressed within the large... Again, if it's over eight pounds, that could be addressed by scientific gap 1, if it's contained in the bag and it's not

taken out. If you've got that one inside round that's been bagged, cooked and then cooled, and it can't cool quickly enough to meet one of the cooling options in Table 1, then it's possible that scientific gap number 1 would apply. But I caution establishments, if you have any question about whether or not your particular process will meet a gap, I recommend you submitting an askFSIS question so that we can review all the parameters. In this type of Q&A I can only give general recommendations.

Speaker 1: Okay. Next question. Various factors can affect the salt contents of brine, such as water temperature or the mixing process, particularly if mixed by hand stirring. If an establishment utilizes salt content or brine concentration as a critical operational parameter, would the expectation be that they would monitor the salt content of the brine, i.e. by using a salometer?

Paul Kiecker: No. One of the key takeaways as we discussed in the stabilization guideline is that when brine concentration is used as a critical operating parameter, it's not based on the ingoing brine. Brine concentration as we're using it, can only be determined by lab analyses of the final product. So you would need to submit some final product to a lab to determine what the salt concentration and free water concentration are. And then you would do the calculation based on those lab analyses to determine if the brine concentration was sufficient.

Speaker 1: Next question. Please speak to nitrite-free bacon. Is there a cooling option other than using a natural source of nitrite?

Paul Kiecker: If you produce a bacon that has no nitrite in it at all, I'm assuming that's what the question is, then you would just use a cooling option that doesn't include nitrite as one of the critical operating parameters. If you fully cook it, then you could use Table 1, Option 1 or 2. Otherwise, you would need to use Table 2, Option 1. Those would be the only... It would be like any other product that doesn't include nitrite and if those don't work, then there may be other journal articles that are available, but within the stabilization guideline those would be the options we have.

Speaker 1: Next question. You mentioned that there is a scientific gap for large mass non-intact products, and that we can use the old parameter of 120 to 55 in less than six hours. Can this be applied to intact large roast beef products? We still probe the center of the largest piece during the cook cycle. If so, is there a document to reference specifically?

Paul Kiecker: Well, in the stabilization guideline we have stated that for intact products you can monitor the surface temperature for cooling. So based on that, even for the largest of mass products, it seems that by monitoring the surface temperature, it's possible to meet the parameters. And so when we developed scientific gap number 1 and discussed with industry without that the major concern was the non-intact products where you had to measure the internal temperature. Measuring the surface temperature should allow processes to meet the options in Table 1.

Speaker 1: Can you explain or expand on minimal equilibration time?

Paul Kiecker: This is one area where we are looking for additional research for these dry cured and immersion cured products. We have been unable to find research that shows how long these types of products need to equilibration time in order to inhibit C. perfringens growth after heat treatment. So we can't really expand more on that because we're just not aware of any.

This is one place where if any establishment or any of the members of academia who are on the webinar are familiar with this research, we'd be very glad to be given that information so that we can improve our recommendations to industry.

Speaker 1: Next question relates to reference slide 72 which states, if there is more than a 1-log growth of C. perfringens, then product may be either re-cooked or microbiologically tested or destroyed. Are there guidelines on the parameters to be applied for the re-cooking process or are the standard guidelines pertaining to the type of products to be used?

Paul Kiecker: Yes, the stabilization guideline in that section does include recommendations for re-cooking because there is the possibility that after the first cooking, the pathogens may be more heat resistant. It's a slightly more stringent time and temperature combination, but those recommendations are present in the guidelines.

Speaker 1: We just had another question come in. We saw that the nitrite and erythorbate were addressed in the cool downs. How does it affect the new cooking guidelines?

Paul Kiecker: I'm not certain what would need to be addressed with the cooking guidelines from nitrite. Could the... If the person who asked the question could expand.

Meryl Silverman: Yeah. And I can just add from the cooking guidelines side, our recommendations generally apply regardless of whether the product is cured or not, or contains natural sources of nitrate and erythorbate. There is one older recommendation for cured poultry to cook to 155. That is a much older recommendation but it is still included in the guidance. So I'm not sure if that's what's being referenced but that's the only place we have a different recommendation for cured, and it's for cured and smoked poultry. Otherwise, the time-temperatures apply to all types of products.

If that doesn't answer the question, just let us know in the chat. Thanks.

Speaker 1: If we use the scientific gap due to large diameter beef items, is it necessary to alert the IIC we are using Appendix B 1999 guidelines?

Paul Kiecker: Well, you would not be using the 1999 guidelines. The 1999 and 2017 guidelines have been rescinded and after December 14th may no longer be used as scientific support. Instead, what you would do is you would reference that you're using the scientific gap Number 1 from the 2021 guideline. And that becomes your scientific support.

Speaker 1: How detailed is the product size parameter in reference to scientific gap 1. Such as greater than 4.5 inches, is that length, thickness or both?

Paul Kiecker: Well, if it's more than eight pounds it would meet it and if the sort of the smallest dimension is at least greater than 4.5, then it would apply. It obviously wouldn't apply to something like a beef stick. That just because it's more than 4.5 inches long, but it's only the diameter of a pencil, it wouldn't apply.

This gap is intended for those products that physically cannot cool quick enough because of their size. It's not for something that's to be used because an establishments cooler is not effective.

Speaker 1: Did I hear correctly that to analyze the brine concentration, you would submit the finished product? For example, ham. If so, what testing would you request from the lab?

Paul Kiecker: We describe that in the 2021 stabilization guideline. Let me see if I can find the page for that for you real quick. It's found on page 18 of the 2021 stabilization guideline. How to make the calculation and that you would request from the lab the total salt and total water from the product.

In addition, we have a processor inspector's calculation handbook, and in Chapter 14 of that handbook, there is additional information on doing this but with brine concentration, it can only be determined with this lab analysis and calculation.

Speaker 1: If an establishment produces wholesale products and retail products, do they have to follow the 2021 updated versions of Appendix A and B for their retail products? For example, the wholesale sausages and retail beef jerky.

Meryl Silverman: Yeah I can go ahead and try to respond to that one. So FSIS guidance can be used as support for any of the products that are produced under FSIS inspection. So those that get the mark of inspection.

If you're producing a product under a retail exemption, which may be the question, we do have guidance about the types of products that can be produced under retail exemption and how those would be subject to state or local requirements. So you'd need to contact the regulatory body over the retail exempt products to understand food code or other requirements for that area.

Speaker 1: Okay, next question. What is the status of the FSIS survey for C. perfringen spores in raw ingredients? 4-log as starting levels is used to limit growth to 1-log. If spore levels are found to be much lower than the presumptive 4-log per gram, for example, 2-log per gram, will tolerance for growth increase to 2 or 3-logs.

Paul Kiecker: Meryl is going to provide an update for that in the next section of the previous webinar.

Speaker 1: Assuming brine concentration has been determined by lab analysis and the pump pickup is consistent, is there an expectation that an establishment would monitor salt content of the brine, as this can vary even when using the same formulation?

Paul Kiecker: If for example, you've determined that the product has the right brine concentration based on the finished product and your formulation made is the same for every batch, I don't think there's any expectation that the salinity of the brine be measured as that itself is not one of the critical operating parameters.

It could be something that the establishment chooses to do, but it's not a requirement. The critical operating parameter itself is the... or part of the prerequisite program would be the brine concentration in the finished product, not the ingoing brine.

Speaker 1: You mentioned monitoring the surface temperature for intact products. Can I use surface temperature for the CUT?

Meryl Silverman: Yes and I can address that for Appendix A. So yes, on the cooking guideline, we do discuss how surface temperature can be used to monitor the heating come-up-time, but we do have a very clear note right underneath that makes it very clear that for the internal product temperature and time, because remember there's two different time in temperature parameters, there's the heating come-up-time, the 50 to 130 in six hours or less, and there's that final internal temperature and dwell time, the 145 for example for four minutes, that must be an internal product temperature because that's what our performance standards are based on, are achieving lethality of Salmonella throughout the product.

So it cannot be a surface temperature for the final internal product temperature, but it can be used for the heating come-up-time and it can be used for the cooling of intact products.

Speaker 1: And then we have a comment. Since the processing climate for dried cured product differs, it would be interesting to see if research can be done via contact of the schools that test our sample, to do a study to give fresh scholar research. For example, the dry curing in Illinois will have different results than

dry curing in Nevada, giving us fresh support over older support that does not consider climate area.

No more questions.

Paul Kiecker: It would be great if that research was done but we're not aware of any such research.

Speaker 1: Okay. One last comment in the chat right now. How often would an establishment need to have their products tested for brine concentration to maintain their ongoing verification? Would formulation records of the brine mixing be sufficient?

Paul Kiecker: Ongoing verification, the frequency of it, would need to be determined in part by the initial validation. And if you find that during initial validation, that the process is highly consistent, you may be able to support a lower frequency of ongoing verification. But if you find that the process is highly variable, then that will be harder to support. So it will really depend upon your specific situation and those specific results you had with your particular process.

And that's the type of thing I'd encourage you to submit through, askFSIS so that we could help you go through your results and analysis to make that a recommendation.

Speaker 1: No more questions in the chat.

Paul Kiecker: With that I will turn it back over to Dr. Silverman.

Meryl Silverman: Thank you. And before I get to the last part of our presentation, Chris, did we have any phone calls?

Chris: I do not see any callers in the queue.

Meryl Silverman: Okay. Thank you. Yeah and I see one other comment came through in the chat and we'll also have an additional time at the end of the presentation for those that are able to stay on longer to answer any further questions. But the last question was for that initial validation you were just talking about, would that be determined via submitting the brine sample?

And yes, the brine concentration, as Scott mentioned, does need to be done by that lab analysis as described on page 18. And that could be done as part of an initial validation and ongoing verification or as Scott talked about could become part of a critical limit or prerequisite program. Ultimately it's up to the establishment how that is addressed in the HACCP system.

And then for all of these, I think there was also a question about whether you're required to share any changes you're making in response to the guidelines with

your IPP. I know you're not required, but we would recommend having these discussions with your inspection program personnel. It's a great weekly meeting topic, in terms of any changes you're making or lab testing so that there's good communication.

So with that, hopefully I have control of the presentation and we just wanted to take the last five minutes to give you some updates and next steps on where we are with filling these scientific gaps. So during the presentations of both Appendix A and B we shared several scientific gaps for which we could not identify scientific literature as support and are seeking more research. To address these common processes, which lack readily available scientific support, we've identified and communicated scientific gaps and are working to facilitate these gaps. So we've posted research priorities on our website to communicate clear research needs with the Agricultural Research Service, or ARS, within USDA and academic researchers.

And we're excited to share some updates on progress we've made. So FSIS has set up an Interagency Agreement with the Agriculture Research Service to complete several studies related to the scientific gaps.

The group has prioritized research and ARS has started studies related to determining lethality of Listeria monocytogenes and Salmonella in low water activity cured meat products, such as country cured hams. And also for identifying acceptable lethality treatments for baked goods that contain raw meat and poultry components.

We're also aware there is a USDA funded project with Michigan State University and the University of Wisconsin, Madison with assistance from the American Association of Meat Processors. It's a large multi-year research project related to some of the scientific gaps in Appendix A and related to identifying alternatives to the relative humidity options for ensuring surface lethality.

So as additional data becomes available, we'll update the recommendations for these scientific gaps with the latest available scientific support. And as I said earlier, we're planning on having some updates for you on these gaps in the next year.

In the meantime, establishments can continue to use the older parameters, again included in the 2021 versions, as support for decisions in the hazard analysis.

And so I know there was a question about our C. perfringens Market Basket Study and we wanted to share an update on that. So you heard Scott talk about the scientific gap related to large mass non-intact products that cannot cool quickly enough between 120 and 80 degrees. And we learned from the 2017 guideline about the challenge for these products, particularly products such as

ready-to-eat turkey breasts and injected roast beef, that cannot be cooled quickly enough to meet the recommendations.

So to address this gap, FSIS started a study between May and September 2021 to assess levels of C. perfringens in federally inspected, ready-to-eat meat and poultry products sold at retail locations. The study was announced in the May 2021 constituent update. The samples in the studies were collected at retail locations and analyzed by the Food Emergency Response Network or FERN laboratories. The results are blinded to FSIS and there was a six month delay period so we recently received the results in March 2022.

Initial results indicated no concerns with the sample results as almost all results were below the limited detection for C. perfringens. So we are analyzing the study results now and we'll use them to assess whether changes are needed to the cooling recommendations in Appendix B for these products. Or we may determine that a larger, more comprehensive baseline study is needed.

So we plan to report the results in aggregate on our website, and we'll have a publication for the literature. In the meantime, again we still have the scientific gap with Appendix B that includes the 1999 parameters to cool those large mass non-intact products, again greater than eight pounds or four and a half inches and that can be cooled between 120 and 55 in six hours or less with that continuous cooling to 40 degrees. So in the meantime, we have that support available in the 2021 version.

And then lastly, just want to share a screenshot of the website where our research priorities are posted to show where we clearly communicate these research needs to ARS and academic researchers. We really encourage researchers to review these gaps and conduct studies to address them. There are such great practical applicability with our guidelines. And again, as that additional support becomes available, we will update the recommendations with the latest scientific support available.

So with that, we really want to thank you for your time and attention. And again just a reminder, if you have specific questions, you can submit those to askFSIS. Again, selecting that inquiry type of HACCP Deviations and HACCP Validation. But again, we are able to stay on for some additional time if there are additional questions in the chat or on the phone.

Speaker 1: Are you familiar with the process of using a data probe thermometer for validation tracking of cooking and cooling, such as temperature modeling of scientific gaps?

Meryl Silverman: I'm not familiar with that but we would definitely be interested in any information you can share with us. Either directly, you can reach out to Scott or I, or submit that information through askFSIS. And we're definitely interested in reviewing any additional information.

Speaker 1: In the 2017 Appendix A revision there is a Table on page four that states, from calendar year 2019 through 2014, FSIS conducted 71,206 salmonella, ready-to-eat product samples and found 38 positives. Would you happen to know if those ready-to-eat samples were also tested for Listeria monocytogenes? If they were tested for Listeria, how many of those 71,206 samples were positive?

Meryl Silverman: Yeah, so all of our ready-to-eat product samples that are analyzed under our RTE prod testing programs are analyzed for both Salmonella and Listeria monocytogenes. I don't have the results offhand of the number of positives, but we do post those on our website. And we also have an annual sampling summary report that includes the number of positives, as well as the percent positive for each year.

So you should be able to find that information on our website. And if you're not able to, please submit a question to askFSIS and we can share those links with you, where you could find that information.

Speaker 1: An establishment is making a ready-to-eat beef strip product that is first smoked overnight at 135 degrees Fahrenheit, then brought to lethality in a fully submerged water tank. The relative humidity is unknown during the smoking process, and the dampers are open. The smoking process uses real wood from logs. Since the lethality is being met during submersion in the liquid cooling-cooking medium, is relative humidity a concern here?

Meryl Silverman: Yeah so that would be a great question that we can answer specifically in askFSIS. Generally, we'd need to look at the heating come-up time, and whether that would fit in the gap or the recommendations around the heating come-up time.

The cooking time in general is considered the time that the product is placed in the cooking oven or heating medium until the lethality time-temperature is reached. So when we discuss the relative humidity options, such as feeling the oven or introducing steam, the 50% of the cooking time or one hour, whichever is longer, would apply to that entire time the product starts cooking until the lethal time-temperature is reach. But again, to answer the specific question, we'd need to look at that in more detail and askFSIS.

Speaker 1: I see no other questions in the chat.

Meryl Silverman: Okay. Do we have any other questions on the phone?

Chris: I do not see any questions in the phone line.

Meryl Silverman: Okay. Well again, we'd like to thank everyone for your time and attention and for joining this morning's webinar. Again, this recording will be posted on the events page for the website. And please follow up through askFSIS if you have any additional questions. Thank you again.

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