Sally Ann: Hey, we're a few minutes after the hour, so I think we'll go ahead and get started with today's public meeting. Good morning, everyone, and welcome to FSIS'S Public Meeting on Reducing *Salmonella* infections linked to poultry products. My name is Sally Ann Iverson, and I will be one of your moderators for today's event. I'd like to get started by going over a few housekeeping items to ensure that everyone is comfortable with the technology that we're going to be using today. We can go onto the next slide. Thank you. For our attendees that are logged on via Zoom, your microphone will automatically be muted when you join. You will see our speakers on camera, but attendees will not have the ability to turn on your camera. Those of you that have preregistered to give public comment and have been assigned a time to speak have been organized into small groups.

When it's your group's turn, you'll need to click the raise hand icon located at the bottom of your screen. You may need to move your cursor to make the toolbar appear. And if you are joining us on a mobile device, you'll need to tap the screen to make the toolbar appear. We'll call on you when it's your turn to speak, and the event producer will unmute you. You'll receive a popup message that you need to click accept in order to be unmuted. We also have a designated time for open comments and questions. If you would like to speak during this time, you may use the same raise hand feature to place yourself in the question queue.

For those who are joining us by phone, you will need to press #2 to be placed in the question queue. You may also enter questions or comments into the chat, and we will get to those as time allows during the open comment period. Well, this is a lot of instructions. We'll be reviewing them again before each comment period just as a reminder. We'll also ask that all attendees, please introduce yourself before asking a question, or providing a comment. You can go onto the next slide.

In addition to the comments provided during today's meeting, FSIS will be accepting written comments on the *Salmonella* framework through December 16th. The instructions for providing written comments can be found in the Federal Register notice and on the FSIS website. We'll also leave the same slide up for a few moments at the conclusion of the meeting, if anyone needs to take down this information. We are recording today's meeting, and we will post a transcript on our website in the events and meetings section as soon as it's available. The comments that are entered into the chat will also be captured as part of that transcript. We can go onto our next slide, and I'll just give a quick overview of our agenda today. After some opening remarks from Deputy Under Secretary Sandra Eskin, the bulk of our time today is going to be devoted to hearing from you.

We'll have four periods of public comment focused on each of the three components described in the salmonella framework as well as the crosscutting issues. During these comment periods, we'll hear from those that have preregistered and been assigned a time to provide comments on that issue.

We've planned three breaks over the course of our meeting today, one in the morning and two in the afternoon. We can go onto the next slide. After we've completed the four comment periods for those that have preregistered, we'll have an open comment period where anyone can get in line to ask a question or make a comment. We are aiming to wrap up our meeting at 5:00 PM Eastern with some closing remarks from FSIS Administrator Paul Kiecker. With that, I am pleased to welcome the Deputy Under Secretary for Food Safety, Sandra Eskin to provide some opening remarks.

Sandra Eskin: Thank you, Sally Ann. Good morning, everyone. Since coming to USDA in March of 2021, I've been clear that we should prioritize reducing *Salmonella* illnesses attributed to poultry products. This meeting marks an important step toward that process. Over the year, we've been engaging with stakeholders, with researchers and scientists and many of you about what actions we should take to drive down *Salmonella* illnesses. Last month, we shared more details about our thinking through a draft framework document that we believe that regulatory strategy outlined there could better protect public health. I want to be clear about what the framework document is and what it is not. It is not a proposed rule. It is not even an advanced notice of proposed rulemaking. It is a document intended to prompt a discussion, a discussion that starts with today's meeting. We recognize that many of the ideas presented in the framework would represent a significant shift in the agency's approach to *Salmonella* and poultry.

That is why we thought it was important that we share our thinking with stakeholders as early as possible so that you all can weigh in on the direction, we're thinking about going. We know that we're waiting results from lots of other key activities, the NACMCF report, a risk profile to risk assessments, and the results of our exploratory sampling project. These will all help inform any future regulatory proposals. But again, we thought it made sense to start the conversation going now. I hope all of you have had a chance to review the proposed framework that was posted on October 14th. It outlines our current thinking about three components we believe are necessary to improve public health, requiring incoming flocks that be tested for *Salmonella* before entering an establishment, enhancing establishment process control monitoring, and FSIS verification and implementing an enforceable final product standard.

Our bottom line is that we want to better ensure that poultry products with levels or types of *Salmonella* contamination that can make people sick are not sold to consumers. We believe that a final product standard would promote salmonella reduction by establishments and incentivize upstream practices that reduce *Salmonella* contamination, including what happens on the farm and in transport. We've also identified several crosscutting issues as part of the framework that we believe must be addressed. So again, I want to emphasize that today's meeting is designed primarily as a listening session for us at FSIS and USDA. We want to hear your views on our draft framework. We want to know what you think is good, where we may have missed the mark, and how you think we can improve our overall strategy. Again, we've decided to share

ideas early. We recognize there are still many, many details, both big and small that need to be worked out and that require the additional discussion that begins today.

Even in some areas you'll see, or you have seen that we have more questions than answers. Your feedback will help us think through details and consider a range of potential approaches. We have assembled a group of FSIS experts who are participating in today's meeting as panelists. They'll be listening closely to the public comments, and they will have an opportunity to ask clarifying questions to commenters to help ensure that we understand each stakeholder's position. I want to emphasize that today's meeting is the beginning of a discussion, and they'll be many more conversations to come. Given that there are so many commenters at today's meeting, there will not be time for you to ask FSIS panelists questions about our proposed strategy. If you have questions, then please put them in the chat and in written comments if you'll be submitting some, and we will certainly consider them.

Because we have so many participants who would like to speak, we want to be fair to everyone and therefore, we must strictly enforce the two-minute time limit. We encourage you to please keep track of time while you're speaking because once you go over two minutes, we will step in, say thank you, and move on to the next commenter. Again, as Sally Ann mentioned, you have until December 16th to submit written comments which can include anything you weren't able to say today. Before turning back to the moderator, I want to express deep appreciation and thanks to the team at FSIS who have worked tirelessly to try to ensure that this is a very productive meeting. Back to you, Sally Ann.

Sally Ann: Thank you, Sandra. All right, so we can move onto our next slide, and we are going to get started with our first public comment. So, this public comment period will be focused on component one of the framework requiring that incoming flocks be tested for *Salmonella* before entering an establishment. Again, we're going to hear from our attendees who have preregistered and were assigned a time to provide comment on this component. As reminders, each commenter has been allotted two minutes to speak, so please limit your comments to that timeframe. If you're still speaking after two minutes, our event producer will let everyone know that the comments have gone over time, and that we must move on to the next commenter. We also have several representatives from FSIS who are on and will ask commenters follow up or clarifying questions. I will introduce our FSIS panelists for this comment period now and ask them to say hello.

So, we have Dr. Kis Robertson Hale, our Chief Public Health Veterinarian, and Deputy Assistant Administrator of the Office of Public Health Science, Ms. April Regonlinski, Deputy Assistant Administrator of the Office of Policy and Program Development, Mr. Todd Reed, FSIS's Chief Operating Officer, and Dr. Hany Sidrak, Deputy Assistant Administrator of the Office of Field Operations. Thank you all for joining us.

So, commenters have been organized into small groups of four. When it's your group's turn, please raise your hand in Zoom, and keep it raised for the duration of your group's time. This will help ensure that the event producer can readily identify you and unmute you to give your comment or to respond to a panelist question. We'll call on each individual in turn, and you'll receive a prompt to unmute. If someone in the group is unavailable when we call on them, we'll move on to the next commenter in the group and come back to them later in the group or at the end of the comment period if time allows. After everyone in the group has spoken, we'll have a few minutes for our FSIS panelists to ask any follow up questions to any of the commenters before we move on to the next group. So, I'll now turn it over to Dr. Hany Sidrak to give a brief overview of component one.

Dr. Hany Sidrak: Thank you Sally Ann, and good morning, everyone. Next slide please. So, for component one, FSIS is considering requiring establishments to characterize salmonella as a hazard reasonably likely to occur at receiving and that incoming flocks be tested for *Salmonella* before entering an establishment. Under this approach, the flock would have to meet a predetermined target for *Salmonella* at receiving, which may be industry-wide or establishment specific, and the establishment must demonstrate that its subsequent process will be effective in reducing *Salmonella* so that the product will meet the final product standard. Next slide please.

Sally Ann: Okay, thank you Dr.Sidrak.

Dr. Hany Sidrak: Thank you.

Sally Ann: We'll now get started with our first group of commenters. Again, if you're in this group, we ask that you please raise your hand on Zoom. And our first commenter will be Ashley Peterson. So, Ashley, you can go ahead and unmute.

Speaker 5: Ashley, a popup may have appeared on your screen. Please be sure to click on it to accept being unmuted.

Ashley: Can you hear me?

Speaker 5: There you go.

Ashley: Oh, perfect.

Speaker 5: Yes, we can.

Ashley: Wonderful. So, thank you Sally Ann. My name is Ashley Peterson. I'm the Senior Vice President of Scientific and Regulatory Affairs at the National Chicken Council. We appreciate the opportunity to provide comment on the proposed *Salmonella* framework. Food safety is a top priority for the broiler industry, and we support changes in food safety regulations that are based on sound science,

robust data, and are demonstrated to positively impact public health. Overall, we are concerned that the proposed framework lacks data to support what would be substantial changes to how chicken is processed in this country, and that FSIS has not completed the two risk assessments that may help us better understand what regulatory changes may actually impact public health. Regarding component one, we are not aware of any data that indicates that requiring a flock meet a target *Salmonella* load will improve public health. While we understand the goal of this component is to incentivize use of pre-harvest intervention, for years, the industry has implemented a multi hurdle approach focused on the continual reduction of *Salmonella* from farm to fork, implementing robust vaccination, bio security, sanitation, and other effective programs.

The biggest concern, however, is the proposed component may negatively impact the welfare of our birds and significantly influence the availability of chicken in the marketplace if in plant personnel refuses or even delays flocks from entering an establishment. This component risk reverting to a long-abandoned command and control approach where whereby FSIS inspectors make decisions about how plants operate. In this time of extreme inflation coupled with ongoing food security challenges, a command-and-control approach will do nothing to improve public health besides removing chicken from the meat case. Finally, we do not believe that rehang testing is an appropriate proxy for pre-harvest testing as there are many *Salmonella* control measures between the time and location of the two samples. Even the agency's own data demonstrates the lack of correlation between HACCP and fecal samples. Rather, we strongly suggest that the agency focus on rehang.

Speaker 1: My apologies, Ashley, you have reached your two-minute mark. We're going to go move on to the next speaker. All right, Michael Barnas, I'm going to go ahead and unmute you. Please acknowledge the unmuting. There you go.

Michael: Good morning. This is Michael Barnas with AHPharma in Hebron, Maryland. One of the concerns that I'd like to express, and I think Ashley touched on a lot of these, is where the samples will be taken if this is going to be at the house prior to the withdrawal period or on the lot, which would have a lot of logistical issues for all of the producers. And I think a lot of folks have done a great job at drawing up the litter and reducing salmonella back into the house so that a lot of the *Salmonella* now is coming from cross-contamination within the processing plant. So maybe focusing on some ways to reduce cross-contamination by doing some different methods of processing might be where our time is better spent. I think that spending a lot more money on sampling is probably not the best allocation of funds when there are things and interventions that can be done back into the house to reduce the *Salmonella* loads. And there are some things that could be done in the processing plant to also reduce the *Salmonella* loads.

Some of the research that we've done here in our lab indicate that the vast majority of the *Salmonella* is within the bird in the GI track and then cross-

contaminated during processing, and that you find very little *Salmonella* on the outside of the carcass due to how dry the litter is and how clean the birds typically are. I think focusing on transportation and some other areas there where we can do a little bit better is probably where our time and money are better spent than increasing the sampling. And then again, I'd just like to reiterate where the sample will be taken. Would it be on the farm prior to withdrawal, after withdrawal? Would it be when the birds arrive on the lot? I think there's just a lot of questions surrounding that and some confusion of logistics as well as how you can rapidly test for *Salmonella* given kind of the lack of technology in that area that can get you an answer within a matter of minutes.

Speaker 1: All right. Thank you for your comments, Michael. We're going to go to Sarah Sorscher. Sarah?

Sarah: Hello my name. Hi, my name's Sarah Sorscher. I'm a Deputy Director at Center for Science in the Public Interest. We are your food and health watchdog, a consumer advocacy organization that for more than 50 years has fought for policies to promote a safer, healthier food system, and we appreciate this opportunity for dialogue and for the leadership FSIS is showing while we rethink its approach to addressing *Salmonella* and poultry inspection. From the perspective of consumers, this is a conversation that is long overdue. While FSIS's stakeholders have spent decades investing in *Salmonella* control, Americans have not yet seen reductions in *Salmonella* illness as a result. And we continue to be sick and hospitalized and killed by this pathogen at unacceptably high rates. We know that poultry is a leading contributor to these illnesses, and we commend FSIS for proposing a regulatory approach and a framework that would ensure food safety and poultry from farm to fork. While risk-based, end-product standards component three are a key to this approach, providing additional standards at pre-harvest and processing are also promising steps and would allow FSIS more opportunities to detect and address potential food safety issues.

Component one, the testing for incoming flocks has potential benefits including motivating producers to adopt pre-harvest measures that are effective in meeting the test and also that establishments could reduce risk post-harvest during processing for flocks that fail the standard. A key challenge for FSIS with this approach is ensuring that the outcome being tested has been validated to predict end-product risk. And without this validation, FSIS runs the risk of driving behaviors that help meet the test but don't actually further public health goals. A second approach that FSIS might consider to promoting pre-harvest practices would be to assign establishments a category status based on whether they are fully requiring, partially requiring, or not requiring a set of validated pre-harvest interventions for their suppliers, such as the interventions already identified in the FSIS guideline for controlling salmonella and raw poultry. Establishments could be subject to increased regulatory scrutiny based on their category status, and this would be similar to the approach FSIS has already taken.

Speaker 1: My apologies. Sarah, you've reached your two-minute mark. We're going to go ahead and move on to the next commenter. Thank you. Kristen, go ahead.

Kristen: Thank you. My name's Kristen Boffo from Walden Local Meat. We are a whole animal meat share company offering home delivery in the northeast and currently partner with over 70 small regenerative farms in New England and New York. A very popular part of our share is the pasture raised chicken. Our farmers move their birds daily to fresh pasture, rebuilding soil health, feed local non-GMO grain, and do not use any antibiotics. While we all understand foodborne illness is bad, given the prevalence of *Salmonella* in a chicken's biome, just think back to the CDC's, don't kiss your pet chicken campaign. The likelihood of an eventual positive on-farm salmonella test for one of my farmers is inevitable. Even though through the use of rotational, regenerative, and small batch methods, the chicken produced by our farmers is wildly different from what one finds in the grocery store and is arguably less prone to the medication resistant strains of *Salmonella* that are making people sick.

All of my farmers that I have shown this initiative to are now second guessing the viability of their farms. Every single one. One farmer told me he couldn't sleep after reading this. Farmers are a special breed. Every day, no matter the weather, the state of the world or if there's a pandemic, they feed this country. Their margins are low, and their work is hard, and they're very resilient. But for these farmers, the addition of the catastrophic financial hit that would result from a positive on-farm *Salmonella* test makes this whole thing not workable anymore, and they're ready to throw in the towel. If regulations like the ones being brought about are put through, I can assure you that many small chicken farms across our country will fold. We will never be able to regulate our way out of salmonella being part of a chicken's biome ever.

Instead, we will lose farmers, we will lose farmland, we will lose gainful employment. Soil health will decline, we'll lose access to clean and healthy food. We will return to big chicken being the only option for consumers, and our nation will run the risk of being brought to its needs yet again due to weakness in our supply chain. I employ you to actually fight salmonella through renewed efforts, teaching safe food handling techniques instead of imposing one that is ineffective and potentially crippling regulations. It will only destroy the small American poultry farmer. Thank you for your time.

Speaker 1: And thank you for your comment.

Sally Ann: Thank you to our first group of commenters. We do have a couple minutes now if any of our FSIS panelists have any comments or questions for those who spoke?

Speaker 2: Yes, Sally Ann. I have a question for Michael. So, Michael, in your comments you asked and kind of talked about where samples might be taken on the farm. And your response implied you might have some information or thoughts about that, and I wanted to see if you could provide some more information or

thoughts to us about your thoughts on the different locations or type of samples that would happen at pre-harvest.

Michael: Sure. Yeah, I was just referring to a study that we did here in our lab where we essentially challenged the birds with *Salmonella* and found that the vast majority of it is in the GI track and was cross contaminating during processing. And a lot of the research even back into the eighties had found that cross-contamination just increases as you further process the bird. And I was just curious as to when the sample will actually be taken. Will it be on the farm or on the lot as the bird is ready to be processed?

Because pre-withdrawal you're going to have presumably much higher amounts of salmonella before the bird has shed most of the contents out of the GI track, and then some of the *Salmonella* will be left there on the farm. So, I think those would probably cause some differences in the samples. And then is it going to be in the fecal where you find a lot more *Salmonella* or would it be in the fecal where you might find a little bit less? I think there's just a lot of nuance there. And one of the speakers I think also had a great point in my opinion, I think *Salmonella* is essentially ubiquitous in birds, and we probably need to promote a little bit better handling amongst consumers. It's probably not as practical to eliminate *Salmonella*.

Speaker 2: Thank you.

Sally Ann: Thank you. Do any other FSIS panelist have questions?

Speaker 3: Yes, I guess I would just to the point about the contamination being the biggest issue being in internal to the gut, it would be great to have access to any literature that's sought to measure differences between contamination on carcasses at live receiving and contamination throughout processing to show the point that was just made by Dr. Barnas. Thank you.

Sally Ann: Thank you. Let's see, any other? Todd, did you have or Hany?

Dr. Hany Sidrak: Yeah, I think that would be great. I don't know if any of the comments so far is in a position to share some of this data regarding the load on the incoming birds or whether is in the guts versus the outside of the bird. I think it's Dr. Barnas that mentioned that he concluded from his study that there hasn't been much *Salmonella* on the outside of the live birds. I wonder if that has been published or something that maybe could be shared with FSIS.

Speaker 2: All right. I have a question for Kristen Boffo. Any chance you could provide a little more information about the pasture raised and if when you provide written comments, if you could provide any information about any data that has been published or publications on that? I think that would be great.

Kristen: I would be happy to. Yeah, so the way that our farmers operate is after time in the brood or the birds are put out onto pasture. So, we are in New England and New York, so our growing season is May to October, but the birds are moved daily to fresh pasture. So, which limits the amount of time that they're exposed to their own fecal matter and that of other birds. They are outdoors, they're eating non-GMO grain they have access to, they can eat grass bugs, grubs and anything they find while they're outside. Our birds are just more robust healthier birds that are just, like I said, not as exposed to fecal matter, which is generally the way that salmonella gets spread. I am happy though to share. There is limited data in the pasture raised farming community, but what I have, I'm happy to share.

Speaker 2: Great. Thank you.

Sandra Eskin: Sally Ann?

Sally Ann: Yes.

Sandra Eskin: Is it okay if I ask a question?

Sally Ann: Of course.

Sandra Eskin: Great. Ashley, you mentioned before your time ended that rehang is not a proxy for pre-harvest. I'm not sure what your next sentence was, but do you have a sense of what you think is a better proxy or some other approach?

Ashley: Thank you, Sandy, for calling on me. Again, I appreciate to be able to finish my comment. I think what we were going to suggest is that the agency does focus on rehang results and then use that information in a risk assessment model that may help us understand what impacts, if any, a change in the load of *Salmonella* at rehang is going to have ultimately on public health. As I mentioned, there's time that goes by between when pre-harvest sample would be taken and when that bird gets to rehang in the processing plant. And there are *Salmonella* control measures both on the farm and I think feed withdrawal was brought up by Mr. Barnas. So, there are control measures that go between the two. So, we just wouldn't want a rehang sample to be indicative of a pre-harvest sample.

Sandra Eskin: Thank you. And provide any and all collaboration in your written comments, and we will certainly discuss.

Ashley: Happy to. Thank you.

Dr. Hany Sidrak: Another question I have is if there's been any studies done regarding the types of *Salmonella* that strains for the incoming flocks. This is something that has been a routine check for some companies out there. And if there's any information on that, that could be useful for us to refer to and consider in finalizing our thought process here at that step of incoming birds.

Sally Ann: Dr. Sidrak, was that a question for a specific commenter?

Dr. Hany Sidrak: That's more of a comment. I don't know if anybody, whether Chicken Council maybe is aware of and perhaps something that could be shared with science.

Sally Ann: Great. Ashley, do you have any follow up on that?

Ashley: Dr. Sidrak, we can certainly look into the literature and provide whatever we can and get our hands on through the written comments, so you'll have what we have.

Dr. Hany Sidrak: Thank you.

Speaker 4: I have a question for Kristen. So, do you have any cost estimates or anything about the cost of farmers? I think you referenced that in your remarks. Can you elaborate on that a little bit?

Kristen: I'm sorry. A cost analysis as in their operating cost, is that what you mean? Or where I said a catastrophic hit?

Speaker 4: Yeah, you said a catastrophic hit, I think. So basically, the impact that you're predicting that would happen as a result of any new policies.

Kristen: Okay. I appreciate. Thank you for allowing me to elaborate on that. So being in the region that we're in, there are not a lot of poultry processing options. We work with two smaller, relatively speaking processors, and they are not equipped to take on if a batch of ours tested positive for *Salmonella*. They don't have the resources to handle a batch like that. And we are not to scale where I could potentially schedule harvest of these birds at a different plant. So, we have farmers that would basically, we would have nowhere that they could process their birds. Which they have put in all the inputs to raise these birds, and now they have several thousand birds that don't have a home. So that's the financial hit. And it's also a loss of income for our processors who are depending on our birds as part of their baseline.

Sally Ann: Okay, great. Thank you so much. I think in the interest of time, we will get moving onto our next group. Thank you again to our first group of commenters and to our panelists for their follow up questions. So, we can have the next slide. All right. So again, if you are in this group of commenters, please go ahead and raise your hand so that you can be identified. And we'll get started with Mr. Thomas Gremillion.

Speaker 1: All right. As a reminder, I'm going to go ahead and unmute you. Please acknowledge the unmuting by accepting the pop-up that just popped up.

Speaker 6: Unmuting by accepting the pop up that just popped up.

Thomas Gremillion: Excellent. Can you hear me?

Speaker 6: Yes.

Thomas Gremillion: Great. Hi, my name is Thomas Gremillion. I am the director of Food Policy at Consumer Federation of America. CFA is really happy to see this framework and particularly component one. Many poultry companies already conduct testing on farm. There was a recent survey of broiler farm managers and veterinarians by Randall Singer and his associates at University of Minnesota, and they found that a majority of respondents, a majority of the broiler farm managers, reported that on farm microbiological tests are conducted to detect *Salmonella* in flocks and. They also found that there were gaps in respondents understanding of poultry pathogens and that many farms were neglecting best practices for reducing pathogen contamination and [inaudible 00:34:06], or at least poultry farms of a certain size adopt some minimum best practices to reduce *Salmonella* contamination. But of course, USDA does not have authority to regulate food safety on the farm.

And so until Congress changes that, I think this is a good approach. The epidemiological data from here and from places like Europe make clear to me that US poultry companies are not adequately investing in on farm controls of *Salmonella*. And frankly, this is a market failure, right? It's a market failure. If poultry companies were responsible for paying the medical bills, the sick leave, the pain and suffering of the people that their products made sick, more would be spent on preventing these illnesses, including on the farm.

Requiring test results for birds in entry will create more transparency and accountability for food safety, including for the two companies, [inaudible 00:34:58] and [inaudible 00:34:59] that produce virtually all of the poultry breeding stock in the US to make the rule maximally effective. FSIS should prescribe standards to ensure that sampling and testing methodologies are accurate.

Speaker 6: Excuse me, Thomas, your two minutes has ended. We're going to go ahead and move on to the next commenter. Thank you. All right, we're going to go to the next commenter Santhosh. I've gone ahead and unmuted you. Please click on the popup to acknowledge your unmuting.

All right. Let me go ahead and try one more time. Please go ahead and unmute and we'll see if the next speaker is available. Next commenter, Rafael Souza does not appear to be logged in at this time nor does Andrew Lorenz appear to be logged in either.

Sally Ann: Okay. I'm sorry. I see Santhosh is just unable to get the unmute.

Speaker 6: Yeah, that's correct.

Sally Ann: Okay and Santhosh you can also use the chat if you're having some issues getting unmuted. All right. And we do not have commenter seven or commenter eight on.

Speaker 6: I did not see either of them logged in.

Sally Ann: Okay. All right. Well then, we have again some time if any of our panelists would like to ask a question of our commenter.

Kis Robertson H...: I guess I would ask Thomas if he could elaborate on the last point he was making before he ran out of time.

Thomas Gremilli...: Yeah, sure. I was going to say FSIS shouldn't... And it sounds like there are some complexities with using *Salmonella* testing at re-hang to verify test results in general, but that verification testing shouldn't be that the sole means of ensuring compliance with this and that standards for sampling and the testing methodologies requiring that the test be done in an accredited lab, for example, that can help to ensure that the tests are accurate. I think requiring the establishments actually genotype the samples, they get it and they're made aware of the levels and serotypes. If they're found in the sampling is a good idea as well because if for no other reason, if a company ends up causing an outbreak that exposes it to lawsuits, it's management...

Speaker 6: And looks like our other commenter has been able to unmute, so we'll just go and allow them to comment. Can you say a few words just to make sure that we can hear you?

Santhosh Venkat...: Is it for Santhosh?

Speaker 6: Yes, for Santhosh, indeed.

Santhosh Venkat...: Okay.

Speaker 6: Go ahead.

Santhosh Venkat...: Thank you team. And food safety is the highest priority. The question that I have is we are a farmer partner ownership company and we have close to 40 farmers who raise birds for us and we are a small operator. In terms of the sampling size, right now we are taking the boots swabs and getting the results. And also after the re-hang we do have multiple interventions, multiple hurdle intervention is what we use. And as of now, I've not had any positives because at that point of time, in terms of the agency trying to enforce a standard with regards to the pre-harvest on a flock, a barn raising 20000 birds, how many birds should I be testing? That's cost-prohibitive for every farmer there.

It's really going to be very difficult in terms of making sure that we are not able to control costs on the barn side as well as on the finished good side. We do

have a predictive prevalence method that we can ensure that we tighten up the processing parameters in terms of having the process control. But in terms of additional testing onto the pre-harvest side, I feel that it is cost prohibitive on the industry side. I do not know about what the other folks are doing, but for our farmers, if we say that this is what's going to be tested out and if it has to be tested out in an accredited lab, nothing is in terms of picking them from the barns, sending the samples, getting tested, getting the results out, nothing is... What exactly is the industry looking at?

Speaker 6: All right. Thank you for your comments. Your two minutes is up.

Sally Ann: Sorry, go ahead Todd.

Todd Reed: Yeah, I have a question for Santhosh. I think you provided some really interesting information and I was hoping you could follow up a little bit more on the testing that you all currently do. So you were mentioning that you do boot swabs on the farms. I'm interested to know how, and if you can provide in written comments later, beyond describing today, but how frequent do you all test on your 40 farms?

Santhosh Venkat...: On every flock.

Todd Reed: Right, so you already test on every flock and what are you checking for on the boot swabs?

Santhosh Venkat...: The prevalence data in terms of whether we have *Salmonella* serotypes, not specific to the three organisms that the agency's after.

Todd Reed: Got it. Yeah, I mean I think if you could provide us feedback on that in writing that we can use, I think that would be very helpful. A cost information as well, because obviously we're trying to do cost estimates, but from what you're saying, it seems like you're describing not different from what we're hoping to hear about.

Santhosh Venkat...: Yeah, because right now in terms of the prevalence data, that gives us an indication in terms of having the process control. But in terms of having regulatory requirements for that, that is something that really would be additional testing at the re-hang. Because after re-hang, I do have inside, outside bird wash before it is going into air chill where I have heavy [inaudible 00:42:53] and after air chill, post chill, I do have secure. The thing is how much more testing is needed? In terms of the cost, the finished good cost is going to be really, really expensive.

Todd Reed: Yeah, I think it'd be great if you can provide us again information about how much testing you're currently doing. And I think that's interesting to find out. And also kind of in... I guess to one of our commenters on the first panel too that was talking about small businesses. I mean, we mentioned one of the

things we're considering is ways to decrease the burden on very small and small producers. And so it kind of sounds like what both of you are describing might fall into that realm as well. So any comments that we could get in writing on that topic would be useful.

Santhosh Venkat...: Perfect. I'll do that.

Kis Robertson H...: I'd also add that it would be helpful to know with the testing that's being done currently at live receiving or on farm, how the industry is using that information, how do you respond to findings of prevalence or levels, if that's even being looked at, what actions are a result from those results that help us? And any data that supports that, those actions are beneficial to lowering *Salmonella* on the final product. That would be helpful to us.

Santhosh Venkat...: Sure.

Hany Sidrak: Yeah. Just to follow up also to Santhosh on this type of data that's being discussed. It sounds really interesting and I just want to add that FSIS would be interested in your findings as far as whether there are some certain high event period throughout the year. Are there any consistencies that you see in terms of the level of *Salmonella* coming from certain houses? You mentioned flock, I'm assuming that is representing a specific grower or maybe a grower has multiple houses. And whether or not it sounds also that you're adjusting your antimicrobials based on that incoming. So that's part also that I want to remind us that we're interested in finding out. How that type of testing that you are doing informs the levels and the hurdles that you have at the processing site?

Santhosh Venkat...: Sure.

Hany Sidrak: Thanks.

Sally Ann: All right. Thank you for the great discussion. So we did receive a note from Mr. Lorenz that he's going to be unable to join us. I do just want to confirm one more time that we still... Commenter seven is still not online, correct?

Speaker 6: Raphael Souza is online now.

Sally Ann: Okay.

Speaker 6: I'll go ahead and allow him his couple of minutes to speak. Please remember to click on the popup that just popped up, Mr. Souza and you'll be able to be unmuted.

Rafael Souza: Hey, how are you doing guys? Thank you for letting me speak. I was a little bit late. I have some technical difficulties to get on internet wise. I missed a great part of it, but one of my main concerns and as you guys were speaking is how fast... And is that a rapid task that can be done to determine when those birds

are coming in and how fast can we do it to manage the birds at the plant to not disrupt anything? Or this bird starts suffering waiting on the truck. Are we going to be testing on the farm? How soon are we going to be testing those birds before they're slaughtered?

Hany Sidrak: Yeah, so I think this is considered so I appreciate the question and I want to say that we're also aware of the present technology and how quickly you could have results on the top of testing. FSIS hasn't really... We'll be taking that in consideration. We haven't really set that pretty solid standard for that. But what we're really interested in at this time is maybe finding out some information, as I probably alluded to on my previous comment back, about how consistent are these results that you're seeing as you have an opportunity to test those flocks before coming into the plant and whether or not there are certain levels of expectations that's... Levels of *Salmonella* expected with each flock. I know that obviously going to depend on the practices from one farmer to another and the level of biosecurity's at the farm level. I don't know if it's all consistent throughout with the exception of certain high events period, I think those are things that will be taking consideration when we finally see how the data will point us in what direction. That's my thoughts on your question.

Rafael Souza: Yeah, I come from the Brazilian industry, the poultry industry as well. And as much as we try to avoid having *Salmonella*, it's there. I mean, we tried anywhere from antibiotics to organic acid to prevent it, but even though Brazil guarantees when they sell product that is going to be absent in 25 grams, it's not the reality. We're just playing a game and then if it happens, it's just gambling. It's impossible to have as of now, it's impossible to have 0% chance that you're not going to have *Salmonella* out on one of the loads, for example. So that's the biggest concern is the disruption on the plant as how busy are when you're slaughtering birds and all of that. So if you can be detected before, yes, and if there's, as you mentioned, if there's a quicker test to test those birds, that would be great to. Appreciate your answer.

Sally Ann: All right. Well thank you again to our commenters in this group and to our panelists for their questions. We are now going to move on to our next group of commenters so we can have the next slide. We did receive a message, so commenter nine is not going to be speaking, so we'll get started with commenter 10. Again, just a reminder, everyone in this group can go ahead and raise their hand on Zoom that will help us identify you and get you unmuted when it's your turn.

Speaker 6: All right, James, you are unmuted. Go ahead.

James McNaughto...: Well, thank you for the opportunity. I'd like to further Dr. Barnes' comments on his technology and what he's doing in a lab. I am the colleague, a colleague of Dr. Barnes and I'm actually working on the [inaudible 00:51:19] area along with him. So what my concentration would like to be is to maybe how to control fecal *Salmonella* as Mike mentioned, the real number there is that we use is more than 98% of the salmonella is in fecal and less than 2% is on the outside of the

bird and the skin mostly and mostly in the neck and the abdomen. So those are...

So fecal is where we've been concentrating on and first of all, you have to control [inaudible 00:52:03] in that bird and before you treat it with antimicrobials or any other chemistry. There's sufficient chemistry out there and what we've done... But the chemistry that is employed on the lab end does cause reduced water consumption. So what we've done is use a dosing system similar to what MDs use on gastrointestinal problems, a dosing system of chlorine dioxide with an acid activator. We'd need to use it more than four parts per million. It's legal up to five and we're dosing that four to eight hours per day. Our hope is that we would pass through that gut three or four times during that period of time, but we would use it...

Speaker 6: My apologies, James. Your two minutes has ended. We'll go to the next commenter. All right, Art, please click on the popup to be unmuted. And go ahead.

Art Lona: Hello, my name's Art Lona. I'm the vice president of Creative Systems Inc. And I'm here to mention our product that we've developed that we believe should help eliminate some of the issues that we're seeing in additional testing, that requires for additional testing. We've basically harnessed a system that is using an environmentally friendly, non-contact, chemical free dry method of decontamination. It's using a high-intensity pulse UV light to achieve this and it can actually be used throughout the process. And we've had very good results in treating *Salmonella* through the processing with raw and cooked products. So we just want to participate any way we can to support producers and the FSIS in this method of additional testing. We're hoping to help actually reduce or control the additional use for testing. So just want to make these comments and we'll continue to listen in.

Speaker 6: All right. Thank you Art. We'll go to the next commenter then. All right Mitzi.

Mitzi Baum: Good morning.

Speaker 6: You are unmuted. Go ahead.

Mitzi Baum: Thank you. Good morning. This is Mitzi Baum with Stop Foodborne Illness and I'd like to thank USDA for having this meeting today. Stop Foodborne Illness is the voice for food safety and we support pre-harvest controls requiring incoming flocks to be tested as part of a comprehensive farm to table approach. This control is in alignment with FSIS's 2013 *Salmonella* action plan to minimize poultry hazards. Application of supply chain principles for live animals is consistent with existing [inaudible 00:55:17] framework. It's not prescriptive, but rather a step in the process to identify and control hazards in raw materials. And of course incoming flocks are raw materials.

We applaud USDA for engaging in this process and want to conclude with acknowledging that this, as with all food and food safety issues, the focus should be on public health outcomes and it's all about consumers and so decisions need to be made with consumers in mind. I know the process can be long. I know there are many different perspectives to be heard and considered, but I urge everyone in the process to keep the consumer in mind because they are the people that are purchasing your products and their expectations are to have safe products to feed themselves and their families. Thank you.

Speaker 6: Thank you for your comments.

Sally Ann: Great. So we'll now have a few minutes for questions from our FSIS panelists.

Todd Reed: Yeah. So I can start, I had question in both for James and for Art because you both kind of were mentioning specific products and just for when we're doing our calculations, if you all can provide any information about the effectiveness of your product and maybe you can talk about that now and also, but in written comments if you can provide costing information, I think that would be useful for us.

Sally Ann: Do we want to maybe... Okay, I see James is unmuted, go ahead.

James McNaughto...: Yeah, I would just make the comment that we were looking for near eradication. Okay. And I know that's a bad word to use, but we're really attacking or trying to attack gut health problems early and also what we find that reducing *Salmonella* by again, dosing with very high levels of chemistry at strategic times during that grow up period and veterinarians know when those times are. But more important at the end, three to five days prior to and during the feed withdrawal period, prior to entering the pre-harvest there, but also further that into disinfecting the crates, which may in fact cause cross-contamination. But also prior to scalding that bird is quite dirty due to death and the excreta that occurs on all deaths and it really spews the material out from the [inaudible 00:58:23] during that time. So we're really trying to concentrate our disinfecting power, pre-harvest, pre-scalding, and then post-scalding prior to re-hang. That's where you're really gathering cross contamination, that's where we're concentrating on.

Kis Robertson H...: Yeah, I'd like to ask or make another appeal for any data or any information that you might have to help us understand how sampling at grow out and the results from tests like boot swabs and grow out, how that might change between grow out and transport and received at the establishment and holding and then entering a slaughter process. If there's any data to help us assess that chain better, I think that would be very, very helpful to us.

Art Lona: Hello, this is Art Lona and adding additional information on the effectiveness of the system we've actually produced some astounding effects on actually eliminating *Salmonella* in the processing plant in a live setting. Obviously we've

done multiple tests in labs, third party labs, and seeing the same results. It's actually a very simple process that can be added over [inaudible 01:00:12], existing conveyor systems and on the raw, because it is controlled temperature so that heat is not an issue, it can actually treat not only raw chicken, but as well as once it's packaged as well. So we have high hopes for it and that's been very effective so far. I'd be happy to provide additional test results as well.

Todd Reed: Yeah, that would be great. Thank you.

Sally Ann: Okay, if we don't have any additional questions, then I think we can go ahead and move on to our next group of commenters. Thank you to everyone who commented in that last group and again to our panelists. So all right, so for our next slide. All right, so if you see your name in this group again, please go ahead and raise your hand so that you can be easily identified and unmuted. And I think I see our commenters lined up, so we'll go ahead and get started.

Speaker 6: All right, commenter, click on the button to be unmuted. And go ahead.

Michael Hansen: Hi, this is Michael Hansen, senior scientist at Consumer Reports. We strongly agree that FSIS should require that establishments both characterize [inaudible 01:01:47] as a quote hazard reasonably likely to occur at receiving, and two, require that incoming flocks be tested prior to entering the establishment as part of their [inaudible 01:01:56] program. In terms of the predetermined targeted receiving, we encourage FSIS to use a measure that tracks human *Salmonella* illnesses associated with consumption of poultry products. Thus using the overall *Salmonella* levels would not be a useful target since it doesn't track with human *Salmonella* illnesses associated with poultry. We also think that the predetermined targets should be different for chicken and turkey. For chicken, FSIS should initially focus on *Salmonella* serotypes and [inaudible 01:02:21] type gallinarum and enteritidis. The three proposed serotypes for the new poultry KPI. For turkey, FSIS should initially focus on serotypes and [inaudible 01:02:30] type gallinarum and [inaudible 01:02:32].

We analyze *Salmonella* data from 2016 to 2019, specifically reviewing FSIS quarterly sampling reports and IFSAC data for annual estimates of the percentage of human illnesses, human salmonella illnesses attributed to chicken and turkey. We then calculated the KPI separately for chicken and turkey and substituting *Salmonella* [inaudible 01:02:52] for enteritidis in turkey. Our analysis shows that from 2016 to 2019, a prevalence rate of *Salmonella* positives declined by over 13% in chicken and increased by over 55% in turkey. The IFSAC data show that the percentage of human *Salmonella* illnesses attributed to chicken increased by 32% from 2016 to 2019, while illnesses attributed to turkey increased by 20%. Applying the proposed KPI just to chicken does link the human illnesses more effectively. The proposed KPI for chicken showed a 23% increase from 2016 to 2019, while the percentage of human *Salmonella* illnesses attributed chicken showed an increase of 32%. Finally, we note that focusing on the three serotypes for the KPI shows that they

compromised 40 to 50% of all *Salmonella* serotypes detected in chicken and 25 to 43% for turkey. Thank you.

Speaker 6: Apologies. Thank you. Your two minutes have ended. We'll move on to the next commenter. It appears that Kelly Gartner will not be joining us today, so we will go on to Chelsie Romberger.

Chelsie Romberg...: Hello, my name is to Chelsie Romberger.

Speaker 6: Please go ahead.

Chelsie Romberg...: Hello.

Speaker 6: Go ahead.

Chelsie Romberg...: My name is Chelsie Romberger and I'm speaking on behalf of Bell & Evans. First, we appreciate the opportunity to comment on this proposed *Salmonella* framework and want to thank FSIS for its continued commitment to public health goals. The proposed requirement that incoming philosophy tested for *Salmonella* before entering an establishment creates a conservable challenge to ensure that all pre-harvest interventions are completed prior to sampling these final pre-harvest interventions such as pH adjustments to drinking water can significantly reduce *Salmonella* load in a flock. So sampling prior to these interventions would result in not having a true representation of the flock load or status at the point of received of an establishment.

The window of time, unfortunately, between these final pre-harvest interventions, catching and processing is very short. So in order to ensure that an establishment is actually analyzing its data, FSIS should consider allowing time for the establishment to evaluate and respond to the results it's seeing. Additionally, there could be food safety or animal welfare risks associated with rescheduling flocks due to these results. FSIS should consider establishment operations before making regulatory requirements that could result in negative impacts to either. FSIS should consider allowing establishments to incorporate instead a surveillance monitoring program to evaluate the effectiveness of pre-harvest interventions, biosecurity practices, and grower management practices used by the grower network, much like an approved supplier program instead of requiring the establishments test each flock prior to received. Thank you.

Speaker 6: Thank you for your comments. We'll go ahead and go to the next commenter. Go ahead.

Steve Roach: Hello, this is Steve Roach. I'm the safe and healthy food program director at Food and Animal Concerns Trust. We're a not-for-profit organization that looks at the impacts of animal agriculture on human health, and also looks at the humane treatment of farms. And in that, we work with a network of small farmers.

We strongly support testing of flocks prior to harvest, and I think the timing of that really needs to be something that needs to be discussed, so you have time where it doesn't create some of the problems that we've heard about it. We worked a lot with the shell egg industry, and with the FDA around the shell egg rule, which it requires testing of farms for *Salmonella* that created a human problem. And I think that worked. And at that time I worked with lots of small farms in a shell egg program that we had, and we were able to have testing work, and with the small farms, without having the catastrophic consequences.

So, I think these things can work, but they have to be done in the wrong way. I think for small producers, FSIS needs to be really clear that the intent is not to prohibit all *Salmonella* in broiler production, but to avoid high levels in strains of public health concern. And I think the small producers shouldn't have trouble meeting that, and there should be some idea of what we can do if there is a problem where you have a strain that's bad on the flocks.

At one time with our shell egg, one of our producers did have DT104, which was a strain that required clear out. So, I think this can work. There's sampling prior to harvest, is been shown to be effective in other countries, so I think it'll work here. So, thank you.

Producer: All right. Thank you for your comments.

Sally Ann: All right. We now have a few minutes for any questions from our FSIS panelists.

Hany Sidrak: Yes. Thank you for the information that's been shared. And regarding how soon in the pre-harvest process FSIS should expect establishments to test for the incoming flock, that is something that FSIS can and will certainly look into and consider.

I guess my question, back to speakers so far, maybe I'll just start with Chelsie, is how, in your opinion or your thinking and experience, how far back, or how much time should be allowed for a meaningful test that would be reflective of what's in the incoming birds, prior to the harvest? If there's any data on that that you could share, with the science?

Chelsie Romberg...: We can share some of the data that we've seen internally in written form upon request. I'd be happy to do that.

Hany Sidrak: Thank you.

April Regonlins...: So, I have a question for Mr. Hansen. So, you mentioned recommendations on specific stereotypes, but do you have any recommendations on levels, too?

Michael Hansen: Well, since we've made clear that whatever the standards should be, should be something that does seem to track human illnesses, since the overall *Salmonella*

levels don't, and I haven't seen any data for studies that show that. For example, the actual quantitative level is linked to human illness.

Just since we did this KPI analysis, and it does seem to track so well, that just seemed like, to us, a good starting point because at least there's some data there showing that there is a link to the human illnesses. Because you can see if you look more carefully, and we'll supply this analysis to FSIS, but for each year you can see that using that ratio of your KPI, works really well, particularly when you separate out chicken and turkey. Because in turkey, enteritidis doesn't occur, so when you swap in Reading, those numbers come out in incredibly well.

And your sampling, and I should say consumer report sampling, the last time we sampled ground chicken, we found for example that the vast majority of serotypes that we found when we were looking were actually the three that you've identified. So, in our sampling of chicken, literally over 90% of them were enteritidis, infantis and typhimurium.

So, focusing on getting those down relatively, since that tracks with illness, just seems to me to make a lot of sense. I mean, maybe you could consider it in... like your performance standards, right, so you have categories. Because it does appear that if we can get those numbers down, that that might actually hopefully track with decreasing human illness. Because that's the only sort of thing that I've seen that tracks human illness so far.

So, that's why we're focusing on that, because there does have to be a link with human illness for any of these things to work, whether it's levels, whether it's specific *Salmonella* types. So, that's why we focused on those three, because the data seemed to show that there is this link.

April Regonlins...: Right. Thank you. Look forward to seeing your analysis.

Michael Hansen: Yeah. We'll get that as soon as possible before the... It just has to go through fact checking. We'll make sure that it gets to FSIS before the end of the comment period.

Todd Reed: Right. Thank you. I have a question for Chelsie. And Chelsie, you mentioned about the challenges of additional pre-harvest interventions that kind of need to happen in those last few days. I didn't know if you could both talk about and maybe provide comments about those interventions, in the sense of if they provide a standard type of reduction, is there a way that mathematically you feel that the agency could take those into account, even if they didn't show up yet in the sampling results? I don't know if my question makes sense.

Chelsie Romberg...: It does make sense. Yes. I think the way that I would respond to that is, we do see different effects from different types of pre-harvest interventions. So, the comment that I wanted to make is, those final ones immediately prior to catch are really important introduction of analysis. So, sampling before those would

not give a true representation, picture of your flock load or serotype, or even the prevalence of *Salmonella*. So, happy to share the information that we have so far in a written form.

Todd Reed: Thank you.

Sally Ann: All right, one last call for any questions from FSIS. And if not, then we'll say again, thank you to our commenters in this group, and we can go ahead and advance to our next slide, our next group. All right. So, I believe we have two commenters for this group. If you can please go ahead and raise your hand so that we can identify you.

Producer: All right. It looks like Devendra Shah is not logged in, but I do see Trey LaPorta.

Sally Ann: Okay, we can go ahead and get started with Trey.

Producer: Trey, you were unmuted. Go ahead and unmute. You should be good to go.

Trey LaPorta: Hello.

Producer: All right, Trey, go ahead.

Trey LaPorta: Sampling for *Salmonella* at the farm level is an unfair burden to the small American farmer. The small farmer cannot be asked to absorb the cost and time and materials associated with sampling for *Salmonella* on their farm. Small farmers already face incredible burdens, rising costs of production, inflation, labor shortage and variability in the market. The addition of sampling procedures, sampling materials, cost of sampling, shipping and lab fees, is a clear financial encumbrance that is unnecessary and inequitable.

During COVID-19, the federal government allocated millions of dollars to strengthen small and mid-scale processors and growers. Contrary to that approach, this current approach, to test for *Salmonella* at the farm level, impedes the farmer's ability to serve his community and grow high-quality protein. The farmer must test for *Salmonella* on their farm. Will there be regulatory guidance on when or how this will occur? The processor must be able to guarantee the farmer's *Salmonella* load can be reduced to minimal levels.

What happens when a processor cannot ensure this? What if the farmer grows his poultry to age, finds out that the flock is tested positive for salmonella, and cannot get it processed? How many processors are going to take the risk of slaughtering poultry that is labeled an adulterant before it enters the plant? Because regulation will take something currently deemed safe and wholesome, and label it the opposite.

If this approach does take place, and a small farmer and processor is faced with attempting to figure out how to control *Salmonella*, we ask that a consideration

be made to investing in technologies and infrastructure necessary to overcome such difficult hurdles. The issue of *Salmonella* is complicated, and there's no silver bullet to eradicate it.

Small growers and processors will need financial and technical assistance in a longer time period to ensure results, but do not eradicate the small American poultry farmers and processors of America. Thank you.

Producer: Thank you for your comments, Trey.

Sally Ann: Okay. All right. Are we still... Commenter 17 is still not logged on, correct?

Producer: I have not seen Commenter 17 log on. No.

Sally Ann: Okay. All right. Do our panelists have any questions for this commenter? And then we might have a few minutes to open it up.

Todd Reed: Yeah, I can start off. So, Trey, you mentioned the very small producers, the small farmers, and obviously we are concerned about that. And so, I was wondering if you had any information or thoughts, or you want to talk a little bit more about the challenges, the cost alternatives? You mentioned more time for phasing. If you have experience on, if you could just kind of talk about that generally?

Trey LaPorta: Yes. Am I unmuted?

Producer: Yes, you are.

Trey LaPorta: Okay, sure. So, we see this affecting the industry from start to finish. So, we see that the farmer is affected, and the risk at the plant is that these farmers will have no place to bring their product. And if the plant does gamble and say they will take it, but cannot guarantee that the load is reduced, and there is a salmonella positive at the end, what happens to that food? That food was once a fine and acceptable product, and now it isn't. So, that burden is huge.

And then, we see the burden of the processor having to make more space, and wait for the salmonella positive or negative alone, and disrupting food safety on that end as well. Because what happens with that product if the processor is waiting?

We also have concerns about the technology that is available to larger plants, but that is not available to smaller plants. We as an industry, and as growers, do not have the same resources. We're small or nimble, but we're not deep pocketed, and we just don't think that we are going to be able to take the same regulations and adapt in the same way.

We have seen a lot of investments in our industries to help us grow and help us become better assets to the landscape of meat and poultry in America, but we

don't see this as helping. We see this as another hindrance to where we have to overcome something that, frankly, the American consumer has been able to take care of by cooking the product in the past. So, that's our stance.

Todd Reed: All right. We appreciate that feedback. And then, I'll just kind of throw a plug out for Sally Ann. I think we may have a question or two that's going to go to all commenters, 1-18. So, anyone else who previously commented, you might stand by, or maybe raise your hand, if you're wanting to be involved in those questions.

Sally Ann: Yeah. So, thanks Todd. We do have a little bit of time again. Just one more check. I'm still not seeing Commenter 17. I just want to confirm that with the event producer as well. Correct?

Producer: I'm still not seeing Commenter 17.

Sally Ann: Okay. All right. So, we have a few minutes, and I think there were a couple questions that, again, maybe anyone who's commented on this component might want to respond to. So, if you do have a response or want to weigh in, you would just need to raise your hand, and then we can identify and unmute you in that order. So, I think Dr. Hale, did you want to-

Kis Robertson H...: Yes. And first, I want to just thank all who have commented for your candor, and for your valuable perspectives. It really is helpful to us. It's a general question. One of the things that we're contemplating is, in addition to overall *Salmonella* - based targets at receiving, also considering serotype-specific requirements.

And so we kind of wanted to just hear from your perspectives, your thoughts, on that as it possibly relates to vaccination or other interventions that would be used on farm to achieve a serotype-specific target at receiving. So, just wanted to see if anyone has any information that they want to provide on the call for that.

Producer: All right. We will start with Thomas. Go ahead.

Thomas Gremilli...: Okay. I'm the winner. I just want to say that I think, for reasons that other commenters, Michael Hansen, others have touched on, focusing on the serotype is important, in part because these pathogens are vertically transmitted. And as I mentioned, I mean, there's two companies that are making all the breeding stock. And if they're not able to get the serotypes of public health concern, that breeding stock, it's going to disseminate through the whole system. So, I'm glad that FSIS is contemplating a serotype-specific standard. Let's start there.

Producer: All right, thank you, Thomas. We'll go and get Ashley's perspective now.

Ashley: Thank you. Can you hear me okay?

Producer: Yes, we can.

Ashley: Awesome. Thank you. So, Dr. Hale, I appreciate your question. I think one of the concerns on the serotype-specific requirements is that we know serotypes shift over time, and so that could potentially become a moving target for the industry. If you're trying to serotype a sample that's a lot more burdensome and takes a lot more time than just quantifying a sample, and then you also mentioned vaccinations. I think it's important to note that almost the entire industry is vaccinating broiler-breeders for a variety of different serotypes. We don't have a commercial vaccine for infantis, for example, and that's been a challenge, or a particular serotype that the industry has experienced over the last handful of years.

But I think that even when we do talk about vaccinations, it's important to mention that though vaccinations are part of a robust *Salmonella* control program, and they are the only serotype-specific tool that we have, it's not going to get us to zero. So, we can vaccinate for enteritidis, for example, and we still may see enteritidis in the processing plant. So, again, while I think it's an important tool, it's certainly not a silver bullet. But I think, again, we can expand upon that in our comments.

Producer: Yeah. We'll go to Michael next.

Michael Hansen: Hi, can people hear me?

Sally Ann: Yes, we can.

Michael Hansen: Hello?

Producer: Yes.

Michael Hansen: Oh, okay. Yeah.

Producer: Yes, we can.

Michael Hansen: I just want to follow up, yes, that like Thomas said, I think the reason to focus on these specific serotypes is two things. I would just point out for enteritidis, Reading, and in infantis there have been studies that have shown, if you look at outbreaks, they can trace it all the way up to the top of the breeding chain. And again, there's only two companies that control layers in the world, there's two companies that control broilers, and there's two companies that control turkeys.

So that concentration, these studies have shown that these serotypes, those three of them that it appears, or in the breeding stock, so that gets spread everywhere. So, that's one thing that I think it's important to do that.

And as for Ashley's concern about how they change over time, again, our KPI analysis shows those three stereotypes for chicken, which is enteritidis, infantis and typhimurium. In 2016, they were 41% of all the *Salmonella* serotypes that were tested. In 2017, it was 44%. In 2018, it's 49%. In 2019, it's 50%. So, clearly, in chicken, these things are going up, and they comprise a large percentage of all the serotypes that are actually being detected. So, that's why I think it makes sense to focus on them. Because it does appear problems are coming from higher up.

For example, in infantis in chicken, it was linked to all these illnesses, but yet there was never any recall. And so, I do think that since these are dominating, and FSIS has already said that's what your KPI is, you should be focusing on those as a percentage, and try to drive those numbers down, and hopefully that will then link to decreased human illness. Because again, I want to just reiterate the fact that this is the only data I've seen of something that is linked to human illness.

I mean, we haven't seen anything, for example, that says a certain serotype at a given concentration is ultimately linked to human illness, so that's why I think it's important to really focus on serotypes and these. And if your own sampling shows that those figures, those three, are a smaller and smaller fraction, then yes, you might have to change that. But the data so far seem to show that those three are really the dominant ones.

Sally Ann: Okay, thank you, Michael. Next, actually, I do just want to clarify. Trey, did you still have a response to this comment, or was your hand up from when you were speaking earlier?

Trey LaPorta: My hand up was from earlier.

Sally Ann: Okay, thanks. So, just a few more hands in response to this. James, would you like to comment?

Producer: Yep.

James: Okay, thank you. And I just wanted to mention the time period. Someone I asked a question. In our minds, we think it takes three to five days prior to pre-harvest in order to get adequate reductions in the fecal. I'm not talking about the chicken house, but the fecal. But I think you could actually go back a little further than that. I'm not sure we got the data yet on that, but we will, where you can define, do you go back eight days or whatever?

And once we get that effective level, both in vitro and in vivo, it does... We've been unable to find a difference in strains. Now, we haven't tested Reading. I'll let Dr. Barnis tell you the others. But we have tested acid resistant *Salmonella* and trying to work on the antibiotic resistant strains. But we think *Salmonella* is *Salmonella*, once you get an effective treatment for it. Thank you.

Sally Ann: Thank you, James. And then, I think we have maybe just another minute or so. I see a hand from Sarah, Sosher as well.

Sarah: Hi. I just wanted to respond to Dr. Hale's question about serotype. We do have these success stories of being able to reduce incidence of illness with particular sereotypes. So, heidelberg has gone down 93% since 1996. Typhimurium has declined 72%. And whether that's vaccination, there's an effective vaccine that's cross protective for both, or if it's sort of general pre-harvest measures that can be taken that target houses that are positive for those serotypes, we don't know. I think both are playing a role.

So, I think there is some value in targeting serotypes and creating incentives around serotype. I think as you work on a system, just being able to design something that's flexible enough to respond when we see new emerging strains, because we know that infantis has risen at the same time those are declining. So, if it's going to be codified in a rule, that is something that is going to be very hard to shift when you get the new outbreak information from CDC.

If it's more of an interpretive rule making what's being proposed for the end product standard, I think that does offer more flexibility. So, I'd want to focus my serotype. My thinking around serotypes is something that can be changed flexibly within the course of a year, for example, based on new info.

Sally Ann: Okay. Thank you, Sarah. And I think with that we are actually right at the time for our first break. So, again, thank you so much to all of our commenters who spoke on this component for your valuable feedback and for discussion. Thank you also to our FSIS panelists for the follow-up questions.

So, we're now going to take an approximately nine-minute break, and we're going to return at 11:45 AM Eastern, and we will get started at that point with our public comment period on Component 2. So, we will see you all back here at 11:45 Eastern.

Mark Williams: Welcome back. It is now 11:45, and we're going to move on to our next public comment. My name is Mark Williams, and I'll be moderating this next public comment period, which will be focused on Component 2 of the framework, enhancing establishment process control monitoring and FSIS verification.

We will hear from attendees who preregistered and were assigned time to provide comment on this component. As a reminder, each commenter has been allotted two minutes to speak, so please limit your comments to that timeframe. If you're still speaking after two minutes, our event producer will let everyone know the comments have gone over time, and that we must move on to the next commenter.

We also have a new group of FSIS panelists available for this comment. They are Dr. Denise Eblen, Assistant Administrator, Office of Public Health Science; Dr.

Phillip Bronstein, Assistant Ddministrator of the Office of Field Operations; Ms. Mary Porretta, Program Analyst in the Office of Policy and Program Development; and Mr. Todd Reed, FSIS Chief Operating Officer.

We'll follow the same format for this public comment, with our commenters organized into small groups of four, with time for our FSIS panelists to ask any follow up questions in between each group of commenters.

When it is your group's turn, please raise your hand in Zoom and keep it raised for the duration of your group's time. This will ensure that the event producer can readily identify and unmute you to give your comment, or to respond to a panelist's question. We'll call on each individual in turn, and you'll receive a prompt to unmute.

If someone in the group is not available when we call on them, we'll move on to the next comment or in the group and come back to them later in the group, or at the end of the comment period if time allows. I'll now turn it over to Dr. Phil Bronstein to give a brief overview of Component 2.

Phillip Bronste...: All right. Thanks, Mark, and hello everyone. So, we're going to be moving on to Component 2 of the framework, which really focuses on ensuring that slaughter establishments are effectively controlling salmonella throughout their operations. And to that end, FSIS may propose to modify its current regulations to prescribe enhanced establishment monitoring procedures, which could include revised locations for multi-point sampling, and the use of a defined method to determine statistical process control.

With that, I'd like to proceed to asking attendees what their thoughts about this part of the framework. Thanks.

Producer: All right. We'll go to the first person on our list. Please remember to identify yourselves when you're unmuted, and to make sure to click on the button to allow yourself to be unmuted. Barbara, go ahead. Barbara, you're unmuted. Go ahead and begin.

Barbara Kowalcy...: Can you hear me now?

Producer: Yes, we can.

Barbara Kowalcy...: Okay. Good morning. My name is Barbara Kowalcyk, and I'm the director of the Center for Foodborne Illness Research and Prevention at the Ohio State University. On behalf of CFI, I would like to express our support for the increased food safety protections in the proposed framework.

Statistical process control, or SPC, has a long history at USDA and in fact, HACCP is rooted in SPC. SPC can be used to determine whether a process is in control, establish limits for monitoring process control, and identify when a process is

beginning to shift out of control. We encourage FSIS to provide guidance to establishments on how to implement SPC using a standardized approach, including how to appropriately conduct the analysis and reliably interpret results. Importantly, the effectiveness of SPC relies on quality timely data collected systematically across the process. For poultry, this would include when flocks enter the establishment, at rehang, post-chill, and so forth.

Understanding the level of contamination at multiple points in the process will help identify potential root causes when processes are out of control. FSIS should work with establishments in developing robust sampling plans that will provide the data needed to effectively use SPC.

CFI is a leader in using statistical approaches such as SPC to improve food safety and has been pushing FSIS to utilize SPC for years. We look forward to working with FSIS to implement these important steps to strengthen our food system and ensure consumer food safety. Thank you very much.

Producer: Thank you for your comments. It appears Davendra Shah still has not joined us on the webinar today, so we'll go next to Chelsie.

Chelsie Romberg...: Hello again. My name is Chelsie Romberger, and I'm speaking on behalf of Don Evans. The proposal to move the pre-chill sampling location to rehang is a step backward from FSIS's goal in enhanced process control monitoring.

The purpose of pre-chill sampling in its current form at its current location is to verify the effectiveness of establishment interventions prior to chilling, such as inside-outside bird washers, LLRs, and other common interventions used in the evisceration process.

By moving the pre-chill sampling location to rehang, establishments would lose visibility into the effectiveness of these critical evisceration interventions, and thereby limit the establishment's ability to respond to unsatisfactory trends in its process controls.

This is particularly of concern to air-chilled facilities that do not have the option of water chilling as an antimicrobial intervention.

Additionally, FSIS's comment in the proposed frameworks that specifying that establishments will sample at rehang would standardize the paired microbial data generated by establishments. In the case that establishments have identical interventions and process controls prior to rehang, such as scalding and singing, which is not true.

We are now seeing that FSIS consider allowing establishments to again incorporate a surveillance monitoring program, that includes routine sampling at rehang, to verify the effectiveness of both pre-harvest interventions and interventions used-

Chelsie Romberg...: By the effectiveness of both pre-harvest interventions and interventions used prior to rehang, instead of requiring the pretrial sampling location be changed. Thank you.

Speaker 7: All right. Thank you for your comments, Chelsie. We'll go next to Thomas.

Thomas Gremilli...: Hello. Hi again. Thomas Gremillion at Consumer Federation of America. I want to start off by just pushing back a little bit against the notion that *Salmonella* illness from poultry is somehow inevitable and will only get rid of salmonellosis after consumers adopt safe food handling practices with something like religious zeal. Again, this is a market failure. The current poultry production practices create a product that makes people sick, and the cost of that illness needs to be internalized by the industry. And that's what regulations for. And the Europeans, particularly in countries like Sweden, Denmark, and the Netherlands, but also looking at the EU as a whole, they've shown that effective regulations can be successful in reducing the illness burden caused by *Salmonella* in poultry. And so I'm grateful that FSIS is taking the initiative here. With respect to Component two, CFA published a report entitled The Promise and Problems of HACCP back in 2015, and that references a number of OIG and GIO reports in turn, that show that the lack of adequate asset plans has been a recurring problem and has been implicated in several serious foodborne illness outbreaks.

And I think this component response to some of the issues that we highlighted in that report, particularly the difficulty that USDA inspectors have encountered when trying to identify problems with establishments asset plans, and when trying to enforce agency regulations aimed at maintaining process control. I think it's important to note that this component is a compliment to final product standards, which we really see is the lynch pin in this regulatory framework. And that indicator organisms, they reflect the overall level of *Salmonella* species pretty well, but they don't indicate whether particular salmonella stereotypes of human health concern are present. And finally, I just want to note that at least one major retailer, Walmart, requires that poultry suppliers submit scientific validations of interventions, but they don't allow APC counts for that purpose. And I think that's something FSIS should-

Speaker 7: And your two minutes are up. Thank you, Thomas.

Speaker 8: And thank you to all of our commenters. Does the panel have any questions for any of the commenters in this group?

Speaker 9: Yeah, hi. I wanted to just get a clarifying question, from Chelsie, on why you think the rehang... Could you clarify a little bit more why you believe rehang is a more appropriate sampling location?

Chelsie Romberg...: I think both sampling locations really tell a different story about the microbial profile of products. And so the rehang sampling would give an indication of

effectiveness of pre-harvest interventions and interventions prior to that point of sampling. But the pre chill sample location where it's currently being taken immediately prior to chilling, is indicative of the effectiveness of interventions from the point of rehanging up to that point. And so, both tell the effectiveness of different process controls and interventions used in different points. So, my comment was just that taking away, or moving, the pre chill sample location from its current place would have an establishment lose visibility to the effectiveness of those interventions after the point of rehang.

Speaker 10: Just to build on Mary's comment, I believe what we talked about in the framework was looking at rehang and post chill and sort of looking at the difference in those, was what was in the framework. So, since you're talking about another point again, which is pre chill, Chelsie, because, of course, you're from your establishment, I believe, doesn't have chillers, so it's pre air chiller you're talking about.

Chelsie Romberg...: Yes, particularly for air chill facilities. We may not have interventions between the point of pre chill and post chill. And so, yeah, to your point, a water chill facility would use that as a primary intervention, but an air chill facility would not have that ability.

Speaker 10: But an air chill would. The active air chilling does have an intervention effect, yes?

Chelsie Romberg...: It does, correct. Maybe just not in the same way that an antimicrobial intervention applied through a water chiller would.

Speaker 10: Yeah. Okay.

Phillip Bronste...: Right, thanks. This is Phil Bronstein. I have a question for Barbara, especially in context with what we just heard there. Through your work with statistical process control and helping establishments kind of react to it and set processes up, do you have any more thoughts, either here or in public comment that you can put in writing, about the parameters that you think would be most useful? Sampling points that are mostly standard or highly standardized in different establishments that we should be looking at as key points of sampling to look at different processes throughout the food production?

Barbara Kowalcz...: Hello?

Phillip Bronste...: Hey, we can hear you.

Barbara Kowalcz...: Okay. I just wanted to clarify. I haven't been working directly with processors, but our group works a lot on translational data analytics in the food safety space. I think one of the things that I've long felt that statistical process control has been underutilized by the industry and that this is something that FSIS should be working with stakeholders to identify appropriate critical control

points where they should use statistical process control. And ideally, the more points that you collect data across the system, the more likely you are to be able to understand when a process goes out of control.

So, for example, I know that there's been a lot of discussion here this morning about testing incoming flocks, right? So, it's important that if you would see a processing establishment have a process control problem, it may be because of a change in the incoming product versus an actual change in their process. And if you're not collecting data at multiple points across the process, you're not going to be able to determine where that is. And it's also important to note that pathogens are heterogeneously distributed within these products, so you need greater sample sizes and more thoughtful sampling strategies to be able to detect contamination if it's truly present. I don't know if I answered your question, but I'm happy to provide additional information.

Phillip Bronste...: It's a complicated question, so I wasn't expecting an aha moment for everything.

Speaker 11: Right.

Phillip Bronste...: And go ahead.

Speaker 11: No, go ahead, Phil. Keep going.

Phillip Bronste...: Oh, maybe for Chelsie, in response to one of the points that Thomas brought up, which was about, some studies indicate that they don't, or some specifications will not take APC as an appropriate indicator. Do you have any thoughts in your own processes or other ones that you may have studied in developing your own process for your establishment? Any insight onto indicator organisms that you think are maybe more useful or less useful than APC?

Chelsie Romberg...: It's difficult to directly correlate APC or EV with salmonella or a specific salmonella stereotype. So, the indicator organism data provides different value. So, we've seen different benefits from quantifying indicator organisms and quantifying pathogens. So, I'm not really sure if I answered that question, but I guess what I would share is just different value and different test types.

Phillip Bronste...: So maybe I can ask a follow up question. From my point of view, I think it's the most important part of the indicator organism is something that's measurable consistently throughout your process. So, it can't be so low that the data you collect isn't able to help you with statistical process controls. So, maybe some of the characteristics that you do look for, and maybe I'll open this up to Barbara, Chelsie, and Thomas. Are there certain characteristics that you think that we should be looking for indicator with understanding that they may not perfectly correlate with *Salmonella*, but they may be very useful in looking at process control?

Barbara Kowalcz...: Yeah, I don't know if somebody else wants to go ahead and answer that question, but I think that this is one of the needs that we have, the research needs that we have, and we've heard that multiple times today, is that we don't necessarily have good indicators. And one of the challenges is that many of the sampling strategies, well all microbiological testing results in the destruction of product. And the lower prevalence, the more samples you have to take to be able to detect it. But it is important for us to be consistently collecting data across the system so that we can look at those correlations. And just as a statistician, I would just remind everyone we have a saying, absence of evidence is not evidence of absence. And so just because we haven't seen some of these correlations doesn't mean they don't exist. It may mean that we just have not collected enough data to show that they exist.

Phillip Bronste...: Well said.

Thomas Gremilli...: If I could just chime in. This is Thomas. I mentioned that the Walmart purchasing specs, really, it's just a flag. This isn't my area of expertise, and I don't understand why Walmart doesn't accept those. But I guess one thought I just wanted to share is that with testing technology changing and rapid testing, we've seen with Covid how you can have these antigen tests that they are very quick. I mean, maybe indicator organisms aren't the necessity they were before. You can just test directly for *Salmonella* with larger numbers. But I'll stop there.

Speaker 11: All right, thank you. I have a different question. So, for Thomas, you mentioned that *Salmonella* is not inevitable, and you talked about it working in Europe. Can you provide some specific information or data on that? What has worked? And maybe talk about it today, but both provide that in your written comments as well.

Thomas Gremilli...: Yeah, certainly. And I'll copy and paste quite a bit of it from the petition that we submitted with consumer reports instead of science and the public interest and others citing examples from Denmark and Sweden. But the main rule that we talked about in a report we put out in 2018 called Taking *Salmonella* Seriously, that Europe has adopted, was passed in 2003 at the EU level. And that requires that the member states formulate these plans for particular serotypes on the farm. And you can look at the incidents of salmonellosis, and it could be just a coincidence, but for me, it's very compelling. So, we will happily submit that evidence in our written comments. Thank you for asking.

Speaker 11: Thank you. Can you maybe follow on and discuss about scalability in the US? I mean, that's obviously different size countries. I don't know if you have any thoughts on that.

Thomas Gremilli...: So I mean, I get the scalability when you talk about a zero tolerance approach and you say, "We're not Sweden." Okay, but how different is the EU from the United States? I think there are more people across the... And we're talking about EU-wide data showing a decline over the last couple decades in salmonellosis. This is an EU-wide initiative requiring member states over there

to focus on these particular serotypes. So, I don't see this being such an apples and oranges comparison. Sure, if we were arguing, and I don't think it's a completely unrealistic argument, but to argue that there should be a zero-tolerance approach like Sweden has taken, sure that's going to cost a lot. But the EU, it has areas that are poorer, it has areas, different climate. I don't think it's unreasonable to say that this group of industrialized countries is doing something that the US can.

Speaker 11: Great. Thank you.

Speaker 8: Any additional questions for the panel?

Speaker 9: Yeah, I had just one follow up question for Barbara. In your comments, you had mentioned for statistical process control, you need quality and timely data across multiple points along the process. So, are you suggesting that we need to have, for a standardized approach, more than two points of testing? Or is that just something would you be providing in your written comments more elaborately on that?

Barbara Kowalcz...: We'll provide that in our written comments, but I think one of the things that, I mean, you need to have evidence of where the critical control points are and where the most appropriate places are to sample. And then obviously if you have multiple points, you can identify where the process is going out of control more readily. And I am not necessarily aware that these have been done in a large-scale way. Maybe they have, I will research that, but the point is, and I believe industry is potentially collecting that data, but has it been analyzed to look across the variety of systems and processes that are in place.

So for example, you might have different levels or different procedures in different parts of the country. Our group, using FSIS inspection data, did find regional differences in some of the inspection results. And so that might suggest either different levels of prevalence in those regions, or it might actually represent different management practices. So, those are the kinds of things that we need to look at when we're trying to do this and when you interpret a process going out of control, one of the things you'll want to do is a root cause analysis. And without adequate data, you're not going to be able to do that quickly.

Speaker 8: All right. I think this is probably a natural place for us to transition to our next group of commenters. As a reminder, please raise your hand if you are in this group. Commenter five, Michael Hanson, you have the floor.

Michael Hansen: Hi, this is Michael Hanson, Senior scientist at Consumer Reports. FSIS has proposed two changes as described in this component linked to poultry slaughter and inspection. The first is to change to points at which samples are collected during their multi point sampling efforts. The second would be to use a more statistics-based approach to process control. We agree that both

changes would have the potential to provide FSIS in the industry additional and possibly better information as to what is happening during this slaughter process. And to help the producer correct possible sanitary processing problems. However, because of differences in equipment, plant layouts, etc., it is difficult to determine how the agency will implement such changes and that they'd be all processing circumstances.

In fact, consumer reports would support not only moving the sampling points, but would urge the agency to consider exploiting additional sampling points based on its own sampling data or other research in order to clearly determine at what point or points does the process deviate from acceptable standards or norms. The second component of this proposed approach bills on passive FSIS's prevention-based approach to food safety. To ensure pathogen control throughout slaughter and processing operations, FSIS may modify the existing requirements for indicator organism testing for process controls and establish additional parameters to better define the required analysis of the data. As part of the proposal, establishes may be required to test for indicator organisms, either APC or enterobacteriaceae. FSIS would consider production body when determining the frequency that establishments must collect samples.

The present guidance leaves the choice of the appropriate indicator to the plant slash producer. Consumer reports would prefer that the agency specify which indicators are required or preferred to accompany the new standard. And [inaudible 01:58:29] are preferred since they have the best chance of representing fecal contamination. And we feel that the new standard provides direction as to the number of samples taken. More would be better for confirmation of process control. Also, it needs to be clearly understood that the changes proposed in this component referred to improving process control using indicator bacteria, and the results are not directly related to the presence or amounts of *Salmonella* in poultry. Thank you.

Speaker 7: Thank you for your comments, Michael. We'll go to Art next.

Speaker 12: Hello. Yeah, this is Art with the Creator Systems. Again, I just want to make comments related to the data. And with our device, we can actually provide real time data reporting that we can compare to the testing and coordinate with testing. This real time data allows us to determine the proper dose for the product that's being processed. If you've seen, it can stop production, correct the dosage and then continue, which basically could prevent product from entering the market that may be tainted with the salmonella. So we have all the tools available to participate and coordinate with the testing onsite. So, some of the things that we use are to determine the effectiveness is the duration of our pulse, the quantity of pulse, the height above the product, and the intensity of the UV exposure. So, those are things we can control. Our system is able and capable, it's just a matter of determining the setting and the location within the process. But all of the reporting is real time reporting, so we expect that to be a nice impact on the testing and the evaluation of the product leaving the plant.

Speaker 7: All right. Thank you for your comments. We'll go to the next one.

James McNaughto...: This is James.

Speaker 7: Hi, James. Go ahead.

James McNaughto...: Thank you. I'll just make a hodgepodge of different comments from what I've heard. I'll remind the group that the integrator, which processes about 85% of the birds in the United States on a contract with the growers. They own the checks and the feed. And so the option is not for the integrator to say, not deny the birds coming into a processing plant. So the integrator's got a high hurdle here and certainly that's part of it. I would stress a point that the CCPs going back to even 21, 28 days as a testing site. At that point, what we find with our data is that if you have *Salmonella* in those birds, you most likely will have salmonella pre-harvest at 45 to 56 days of age. And so that's not a complete story there, but it's certainly an additional site that should be looked at.

We also find that there's a great correlation, huge correlation between gut health and the salmonella loads going into processing plants. So monitoring, we as a company, our company, AH Farmer Incorporated, not the chicken industry, I don't represent them, but we certainly would like to see HACCP up move backwards into the grower house and develop CCPs along that line. I will tell you that the strains of salmonella is most likely will not change also at after 21 days of age. So it's plenty of time to correct the problem if you have it. And we can do so, thank you.

Speaker 7: Sorry, James, your time has ended. Thank you very much for your comments. All right. We'll go ahead and see. Santhosh is ready for his comments. All right, Santhosh, go ahead and make sure to click on the button to unmute yourself. Perhaps he doesn't have any comments at this time.

Speaker 8: Okay, so thank you to all of our commenters. Does the panel have any questions for this group?

Phillip Bronste...: I'll start one for Michael Hanson and then maybe if anyone else wants to chime in about their thoughts after that. So, obviously making national policy is very difficult when we have hundreds of establishments that are doing their process and by HACCP, by the rules of HACCP, they have their ability to innovate on and have their own processes in their own way. They think they're going to control the hazards the best. So, I heard you thinking that we should be more prescriptive as an agency, and I think that while I understand the point, it does become challenging also. So, maybe I can ask another question. Do you think that instead of being prescriptive, for instance, on the type of indicator organism that we are more prescriptive on the characteristics that we would want to see from an indicator organism. For instance, it should be measurable at all points in the processes and the processes can be defined maybe loosely or maybe more definitively. So, your thoughts on the saying specifically this

indicator organism or this step or in this area that satisfies these parameters, do you see those as being an acceptable interchange or not?

Michael Hansen: Yeah, that would be fine. The only reason that we suggest using something from enterobacteriaceae because it's more likely to indicate fecal origin, that's all. In terms of the number of samples. It would be better, as we said, to do more, but this should all be based on the data you have or that you can find of how much sampling would actually be useful. We understand that it can cost too much and perhaps be too prescriptive, but there should be something that, particularly if you're doing statistical process control, where you can actually show that there's declines in the sanitation or cleanliness in the plan. So whatever you can do to get that, to move forward and work and to show statistically that there are reductions, that's what we'd like to see.

Phillip Bronste...: Thank you.

Michael Hansen: That does give the companies or the plants some leeway, but they should have testing that is statistically valid enough to be able to show improvements.

Phillip Bronste...: Thanks Michael.

Speaker 11: I can go next. So, for James, you mentioned, you talked about the correlation between gut health and *Salmonella* loads. Do you have any information on the correlation between salmonella in the gut and what's found through maybe surface testing or other types of testing?

James McNaughto...: Okay, sorry. There is a very strong correlation and in gut health and *Salmonella* loads and as well as, immune system and there's many different factors there. So I'm not sure I'm exactly answering your question, but there is also a strong, when we do test, we'll test all the way from seven days of age through the pre harvest and then follow those birds through processing. It's more difficult, it gets more cumbersome to get processing data off of those trials, but it's certainly reducing that load throughout the lifetime stews that curve downward. And it's much less likely to have salmonella at pre harvest when you don't find it at 21 days even.

And because, on the live end, that's when bird stops eating litter, it knows what feed is, it knows what nipple drinkers are, and so they're going along with their life in a comfortable way after 21 days without consuming fecal or bedding material. So all of that's important, but it does give the integrator and it's the integrator, not the grower that would dictate this. It does give the integrator time to correct the fecal problem. I'm not sure I answered your question. Sorry.

Speaker 11: What you provided was great. Thank you.

Speaker 10: I just had one question. I think it was Mr. Hanson brought up about production volume. There's going to be very different size flux across the nation coming in

for slaughter. Any thoughts on production volume and how that it might impact what we're doing or what we're thinking about here?

Michael Hansen: Well yeah, I mean obviously if the production volume is five or 10 times different, then the total amount of samples should be higher in those so that there is a rough amount. Because the idea you want is you want to get some idea that you're roughly sampling the same for the number of samples and the total product produced. That's all we meant by that. So that no, you wouldn't expect to see the same number of total tests done in two different plants that have tenfold differences in terms of the amount of product they're moving through.

Speaker 10: Sure, that makes sense.

Michael Hansen: That's all so, yeah. Thank you.

Speaker 11: Yeah, I have a question, but real quick, just for James, if you can submit written information about the different time periods and what you're finding or links to publications or data, I think that would be really helpful to us. And then for Art, I have a question. You talked about real time data and reporting. Just curious, how do you define real time? And then are you talking about testing program? Intervention program? Reporting? What exactly were you saying that that is possible in real time?

Speaker 12: Yeah, so our system, as it runs throughout the duration of the day while the processing is going on, we're connected to our system. So we dialed in the parameters that we know are eliminating or highly reducing salmonella on the chicken, on the raw chicken. So, we have those parameters dialed in as long as those parameters are where they're supposed to be. The intensity, the light is primarily the main component. As long as we know it hits that mark there, it should achieve the results. So if we see the light dim any, the amount of exposure change. We've already designed it to stop and the production so that in the event this happens, we can repair it, figure out what the error is, and get it back up to running operation, and start production again. So what we're doing is matching that exposure to the tests so that we've coordinated... That's how we figured out what the dosage needs to be to hit the mark. And we can change those parameters based on speed, based on product, based on what we're treating for. In this case, it's been *Salmonella* that we've been very successful with. And a lot of times, high kill rates as well as elimination even, so I'm hoping I'm answering your question.

Todd Reed: Yep, it did. Yes. Crystal clear what you're saying. Thank you.

James McNaughto...: If you got a minute, this is James. I will send you a lot of information, a lot of trials, but I will say that we both work in both water and feed, so the reaction to killing *Salmonella* in the fecal, it works a heck of a lot better on the water side, which typically is not what the integrator works in. He likes working in the feed

only, but that philosophy is changing, and will change, and it's a changing world for the integrator at this point, but we don't want to forget water treatment or salmonella. I can tell you that.

Mark Williams: So it sounds like this conversation could go on, but we need to move to our next group of commenters. So as a reminder, please raise your hand if you are in this group. Commenter nine, Lam Nguyen, you have the floor.

Speaker 13: All right. I am not showing Lam at this moment, so we'll go ahead and see if Michael Hogan has joined. And there he is. Fantastic. Go ahead and make sure to click on the prompt that says, "Allow to be unmuted."

Michael Hogan: Can you hear me now?

Speaker 13: Yes, we can.

Michael Hogan: Okay, great. This is Michael Hogan, Chief Scientific Officer PathogenDx. We submitted a reasonably detailed, written commentary, but I'm just going to talk over it and give you the two-minute story. We basically agree greatly with the idea of the FSIS proposing that we set regulations to greatly increase testing, both the positioning and frequency of testing. But we did note that as part of the proposal, that there would be requirements for total aerobic plate count, internal bacterial testing. And so, our comment is that we agree greatly that this is a good thing to do, but we just wanted to clarify that a number of technologies are out there, including ones we're working on, to obviate the need for standard plate-based analysis. And we just wanted to put our two cents worth in there, and we did so in writing in a bit more detail, that a good argument can be made that there are fast, nucleic acid technologies that are out there, that are currently being used and AOAC approved in other areas for blood class indicator analysis, total aerobic BTGN, internal bacteria, and even drilling down to individual species.

And these can be all pretty much at the same time. And the idea being that if the field has been operating in the rear-view mirror for a long time, it takes several days to get the kind of culture-based data that I think would be useful. And so, the question is, if it's now possible, flash forwarding from the 21st century, so to speak, if you can obtain the information about broad class, presence of aerobic and internal bacteria, and even individual species, and get that data in a small number of hours, as opposed to a small number of days, an argument could be made that something a lot closer to real-time data acquisition could be much more useful than trying to infer, based upon data that's accumulated three days in the past after an ordinary plate culture, so that's all I'm asking.

Speaker 13: Sorry to interrupt, Michael, but your two minutes is up. Thank you. We'll move on to Ashley Peterson next because Melissa currently has no comments. So Ashley, your turn.

Ashley: Good afternoon. We wanted to start by discussing CDCs National Outbreak Reporting System, or NORS, as this data is relevant to the proposed framework. From 2009 to 2020, NORS reports just over 15,000 poultry-related *Salmonella* illnesses, which represent almost 30% of all salmonella illnesses. However, almost 8,500 of the 15,000 poultry-related illnesses were attributed to live poultry, for example, handling chicks or interacting with backyard flocks, and not related to chicken consumption at all. Chicken consumption accounts for just over 5,000 cases, which represents less than 10% of all salmonellosis cases in the US from 2009 to 2020. While the industry is dedicated to drive this number down even further, there is a failure to distinguish the sizeable contribution of illnesses due to exposure of live poultry, and to account for the significant increase in chicken consumption in the NORS data. In fact, salmonellosis incident rates attributed to chicken have decreased if chicken consumption patterns are considered. Specific to component number two, the industry uses a variety of approaches to ensure process control is being maintained.

Following longstanding asset principles, these approaches are establishment-specific and uniquely tailored to each plant's process. However, as proposed, a framework would abandon these asset principles and force a command-to-control approach to process control monitoring by dictating how, when, and where the industry is to perform testing. The industry is and should be expected to control pathogens, but there's not a one-size-fits-all approach in doing so. Overall, this approach will stymie innovation and technology, which seems counter to a collaborative food safety approach. Instead, FSIS could consider conducting verification sampling at the locations they feel appropriate, and let establishments develop their own individual testing plans. FSIS could use verification sampling results to include enumeration results in a risk-assessment model to help us understand what impacts, if any, changes indicator organisms and/or *Salmonella* load at various processing locations we'll have on public health. Thank you.

Speaker 13: Thank you for your comments, Ashley.

Mark Williams: Before we move to the panel, did Lam come on the line?

Speaker 13: I have not seen Lam on the line.

Mark Williams: Okay. Well, thank you to all of our commenters. Does the panel have any questions for this group of commenters?

Mary Poretta: Yeah, just a question for Michael Hogan. You had mentioned that these new technologies... What would the cost of those technologies be compared to the standard testing? Do you have any information on that?

Michael Hogan: Yeah, we can send more information, but it's comparable, particularly when you take into account the labor that's associated with plate-based work. I think a lot

of people tend to fixate on the cost of film or whatever for doing Petri testing, but the fact of the matter is that the labor is the real cost. So yeah, in the written response that we had, we've provided some of that, but we'll provide some additional information, but it's comparable. It's no more than a real cost of doing plate-based analysis and is really quite a bit more faster. These would all be culture-free analysis, and therefore would not be limited by 24 or 36 hours of culture before the data is obtained. So we will provide additional information to you.

Mary Poretta: Great, thank you.

Phillip Bronste...: So I have a question for Ashley. So Ashley, I appreciate the comments that you've said here, and I think that the intent of Component two is to try to put some bounds around process control, not necessarily. Our intent was not to stymie innovation. But having said that, are there things that knowing the variety of establishments that are out there and the varieties of ways to produce a safe product in the market? I'll ask a similar question that I asked of Michael Hanson is that, can you foresee the agency proposing something that talks more about the characteristics and maybe the methodology of sampling and process control? Which would still allow for innovations, but allow us to have some control that we can, I guess we would say, compare establishment to establishment, to make sure that they are all taking into account process control and reacting appropriately to it.

Mark Williams: Before we go to additional panel questions, I think Lam is now on the line.

Speaker 13: Hi, Lam. I have selected you to be unmuted. Go ahead. If you want to make your comment, click on the popup that just appeared to allow yourself to be unmuted so you can make your comments. All right. I did click on Lam to be unmuted, so we'll just keep going on, and hopefully they'll unmute. Until then, we can go continue with the questions.

Mark Williams: Okay, so I think Phil had a question for Ashley. Want to give you time to respond?

Ashley: Can you hear me?

Mark Williams: Yes.

Ashley: Okay. Perfect. Thank you.

Phillip Bronste...: We can.

Ashley: Dr. Bronstein, I think that's a great question. And the agency already has a testing frequency requirement out there for industry at one per 22,000 birth pre and post chill, so that's something that the agency's already put out. I do want to agree with Barb Kowalczyk's comments earlier about maybe a compliance

guide, or I don't know what that would look like necessarily, but some way to help industry implement a more robust statistical process control model. And so, I think that's something that we could all work together towards accomplishing. And I understand the agency's desire to want to, and I'm using air quotes, compare establishments so that they use the same indicator organisms, for example.

But again, I think it's fundamentally up to the establishment to demonstrate what works for them, because it's going to be... every establishment has to verify that an indicator organism is going to be indicative of process control and established parameters in that. So I don't know if I would necessarily support a requirement for certain indicators. We only have a few that we have available to us, so perhaps we need some more research on alternative indicators that we've not necessarily considered in the past, but I do think some assistance with SPC would be warranted.

Phillip Bronste...: Thanks, Ashley.

Mark Williams: Okay, before we go to the next question-

Dr. Denise Eble...: I had a question. I just wanted to say something to Ashley too. So Ashley, thanks for sharing the NORS data with us. And you're right, that does refer to that is all, illnesses including the backyard flocks, but the IFSAC data, the Interagency Food Safety Analytics Consortium looks at... it does exclude the backyard flocks from the calculation of attribution of illness, so it is just looking at the food and it doesn't include those birds, those backyard poultry illnesses in there. Just wanted to clarify the difference in those two CDC data reference.

Ashley: Yeah. Thank you, Dr. Eblen. I appreciate that. And again, I was just talking about the NORS data.

Mark Williams: Thank you so much. We're going to go ahead and bring commenter 15, Trey LaPorta into this conversation. So Trey, could you go ahead and raise your hand? It looks like Phil has a question. We'll go to Trey right after that, the question and answer, for his two minutes. Go ahead, Dr. Bronson.

Phillip Bronste...: All right. I think I'm okay right this instant. Yes, please go ahead, Trey.

Mark Williams: Okay, Trey LaPorta, we'll go ahead and go to you. You'll have the floor for two minutes.

Speaker 13: Trey, you're unmuted. Please go ahead. Trey, check to see if your microphone is unmuted. All right, I'm going to try un-muting. And go ahead and un-mute yourself, Trey, and try speaking, please.

Mark Williams: Okay, we can continue with the conversation, and if Trey can look to see if he can unmute his line, we have enough time to allow him to jump in and give his

two-minute statement. But Dr. Bronstein, I think you had a question. Let's go ahead and go with that question now.

Phillip Bronste...: I think I'm good before I [inaudible 02:27:47].

Mark Williams: Okay. Does any other member of the panel have a question or comment? Okay, before we transition, let's see if Trey was able to unmute himself.

Speaker 13: All right, I'm going to try one more thing, and then see if that'll help, and see if we can get him unmuted. All right, Trey, click on the button to be unmuted. All right, Trey, can you say a few words, see if we can hear you. All right, looks like we can't hear Trey at the moment. So Trey, my suggestion would be possibly logging out and logging back in again, and maybe that will help later, but we can continue until that time. And you can also post your comments in the chat.

Mark Williams: So let's move. Does any other panelist have a question or a comment for any of the commenters during this component?

Dr. Denise Eble...: I have a general comment. We've heard a lot from the different commenters about how this is going to be really difficult to do with the huge amount of plants that there are and the different... every plant is different. No plant is exactly the same. So any comments on how we might do this? Again, this is our proposal. So how might we do this? Because process control is clearly very important. It's the center of making safe food. And how might we do this then, if we're not... Because if we look just at generic E.coli, You get a lot of zeros, and that gives a really false sense of security. So how might we do this? Any ideas on how? We've heard a lot about the problems with this, and the snags, and the drawbacks. Anybody got any suggestions for what might work?

Mark Williams: Anybody that wants to speak, they can please raise your hand, and we can give you the floor.

Barbara Kowalcz...: Hey, this is Barb Kowalczyk. Thank you, Denise, for the question. I think that implementing statistical process control is certainly doable in any size plant. The question is building capacity to do those things, and you don't necessarily... There is so much we don't know about which indicators there are that might give us more information even than microbial testing. We do have a challenge with microbial testing because a negative doesn't really mean a negative. It's a non-detect, right? And it may be that due to the way you sampled, due to the testing method, there's a lot of reasons that may be a non-detect.

But I think there's more research that needs to be done into this, and this is where data sharing among the public and private sectors is really important, because as you get larger data sets, you can actually mine those data sets to understand where certain interventions and certain critical control points might be more important or more indicative of process control than in other situations. I would never say that their... Food safety is not a one-size-fits-all

approach. We know that. And one of the challenges is, unless you have large, aggregated data, it's hard to parse out where certain interventions might work better. Thank you.

Dr. Denise Eble...: Thank you, Barbara. That's a really good point. The more data we can have on this, the better. And I know that the industry, they always say food safety is not a competitive space. Sharing data like this would really help us as we do our risk assessments, and as we look at what data is out there so that we really do have a good idea of what's going on in the plants, across the spectrum, of different establishments that we regulate. So that's a very nice point. Thank you.

Phillip Bronste...: Dr. Peterson.

Speaker 13: All right, we'll go to Ashley.

Ashley: Thank you. And again, great question, Dr. Eblen. I do agree with Barb on SPC. And again, I mentioned this earlier, but I think we have an opportunity to help educate on what SPC is, how it can be implemented, and that may help bolster process control monitoring. We also, I think, still need research and supportable information on indicator organisms. We have to support whatever indicator organism we choose to use. So additional information and research on those, or maybe there's something there that we haven't seen before or haven't used before, that we need to consider. But again, I think FSIS could, as I mentioned, consider conducting verification samplings at the location the agency feels appropriate, letting the industry have their own testing plan, which is going to be unique to each establishment.

And then, that data, the verification results, which could include salmonella enumeration results, use that information in a risk-assessment model that can really help us understand what impacts changes in indicator organisms and/or salmonella load can ultimately have in improving public health. And Dr. Eblen, I know you and I have talked about this at length, and we're going to talk about it in the crosscutting sections, but I think data sharing and trying to determine a pathway forward on that is also a very valuable tool that I want to continue to pursue with the agency.

Dr. Denise Eble...: Absolutely. Thanks, Dr. Peterson.

Phillip Bronste...: So I'd like to respond a bit and maybe ask some more questions. And then, I think we have a moderator, I think James Kent and Michael Hanson have their hands up. So I don't know if they can speak after this too, but in the meantime, I think there's a couple of pieces that are interesting there. Number one, I think I would like to talk about... I don't know that we need to necessarily say any one indicator organism. If you look across industry and the data that we've seen and heard about, different establishments definitely have different indicator organisms which work better or worse for them. And some establishments, the level of ED is just not high enough. We get a non-zero number. And I think that's

really one of the pieces about process control, is that it's a, depending on the frequency, and especially if you do it at higher frequency, you have the ability to assess your system, react to your system when it starts to trend out of control, and take corrective actions before you have an adverse public health effect out there.

So I think that's really important. And I think that the agency will definitely be doing verification and verification sampling, most likely, at specific points. But I think that's going to be a relatively rare chance the FSIS would go, compared to the amount of sampling that some establishments do, right? We take one a week, versus maybe multiple times a day in some establishments, where they're taking samples for statistical process control. So I do believe the agency would be looking into doing verification sampling at some frequency, but that would be more just to the point verification, and we would really still be relying on establishments, knowing that they're taking these samples, proposing to take these samples, and reacting to them on a much more frequent basis than FSIS would potentially be taking samples.

Barbara Kowalcz...: Can I respond to that?

Phillip Bronste...: Oh, certainly.

Mark Williams: Go ahead, commenter.

Barbara Kowalcz...: This is Barb Kowalczyk. I agree with what you're saying. I think one of the things that's really important is that, especially for our small and very small establishments, they're not necessarily going to have the capacity to conduct the kind of research or analyses that they need to identify which indicators work best for them. And as with any new initiative, I think it's really important that FSIS invest in extension and really work with the extension arm of the land-grant universities to build capacity in the small and very small establishments. Also, this is another reason why aggregating data is really important.

If you can aggregate observational data, not experimental data, I'm talking specifically observational data, collect it across the industry, you can, through mining that data, provide better guidance to those small and very small establishments potentially, on how they might attack. Which indicator organisms they might focus on, and how they can tackle statistical process control programs in their establishment. So I think that it's just really important that the agency work with extension and... Not just work with them, fund them, so that they can provide this guidance to the small and very small producers. Thank you.

Phillip Bronste...: Thank you. I agree and noted, so thank you. James Kent?

James Kent: Yes, sir. Can you hear me?

Mark Williams: We can hear you.

Phillip Bronste...: Yep, got it.

James Kent: My name is James Kent. I'm the owner of KTT Plastics. It's a patent and trademark product that I came up with for food safety. And for the last year, I've been going back and forth with government officials. I think this product needs to be mandated immediately because it's the consumer that suffers. I think that 100 million plus households in this country should have a box of KTT Plastics. And I think that Mr. LaPorta, and it's almost three hours had the most telling testimony. He talked about the small farmers and the small processes. And that's really the elephant in the room, and one of the reasons I came up with KTT Plastics, because nobody wants to talk about corporate greed. We're losing 3,000 people a year, just do that times the last decade.

That's 30,000 lives, over 480 million sick, 1.2 million hospitalizations. It has to be about the consumer, it has to get down to the consumer. And I think KTT Plastics is the answer, and I think it should be mandated by law immediately. Immediately. Some may not agree, but like I said, I think in this almost two hours, Mr. LaPorta had the most selling testimony. He went over and over again about the small farmers and the small distributors, and they're just not going to... It comes down to money, but if the product is in a home where the consumer can test the food before they eat it, I think it would go a long way in saving a lot of lives. So, that's just my take.

Phillip Bronste...: Thank you, Mr. Kent.

Mark Williams: Thank you so much for that. Was there any other commenters from this component who had any final questions?

Michael Hanson: Yeah, this is Michael Hanson from Consumer Reports. This is just very quick. I basically just also want to throw my support behind what Barb Kowalczyk said, and that's the need to do guidance, particularly, to the small and very small plants on statistical process control, and try to do both research and gather as much data as possible throughout the industry, so that with larger data sets, you can help advise people more. But just again, to throw support behind the need for FSIS to come up with the guidance on statistical process control for all these plants, so that they're properly doing that. Thank you.

Phillip Bronste...: Thank you.

Mark Williams: Okay. Any other... Just before I go to the next round of commenters, anyone else from the panel have any comments? Okay, I see Mr. LaPorta. You have the floor.

Trey LaPorta: Can you hear me now?

Mark Williams: We can hear you.

Trey LaPorta: Great. I'm going to go ahead with my comment. Is this the appropriate time?

Mark Williams: Yes, sir. You can take your two minutes.

Trey LaPorta: Okay. Small and very small processors are being asked to bear new and higher costs associated with pathogens that, by the USDA's admission under the proposed rulemaking, originate at the farm. Small processors will not only need to hire employees to ensure farmers are producing live animals free from *Salmonella*. They'll have to hire additional staff to sample more frequently, mechanics to maintain new equipment for chemical application, laborers to administer more chemicals and sanitation procedures, and qualified persons to conduct sampling and analyze data. In the USA, small and very small plants already face many hurdles that large plants do not face. Most utilized laborers do jobs that are mechanized in larger plants.

The same technology is simply not affordable or available to smaller plants. If a small processor has any chance at survival under this regulation, they must be extremely cautious in their approach to accepting live animals. If a processor is slaughtering animals for a fee, they'll lose out on hundreds of thousands of dollars by not accepting lots that have tested positive for *Salmonella*. If they do accept a lot and cannot lower the salmonella load, both the farmer and the processor will face financial burden of condemned lots. Most small and very small processes in America do not have methods of remediating *Salmonella* - positive chicken so that it may be considered wholesome. Large processors, however, do have ability to divert product to be cooked. If the process includes having to hold back product in weight, many small processors would have to store product, and have to be burdened with the cost of doing so.

That cost involves more materials and space to store items that would otherwise be in commerce. This involves cost of plants, including remodeling and equipment. The biggest piece is that fresh poultry is only fresh for a limited time, and a holding period waiting for *Salmonella* results will diminish the small processor's ability to compete in the fresh marketplace. This proposed rulemaking will put all of America's small poultry growers and processors in jeopardy. The risks involved outweigh the reward. Simply, too much burden is being put on small processors when salmonella begins its journey in the egg and ends its journey in the oven, where if cooked properly, it is finally eliminated. Thank you.

Speaker 13: Thank you, Trey.

Mark Williams: Anyone from the panel have a question for Trey?

Dr. Denise Eble...: So Trey, do you think with... Is there an opportunity for USDA to work with the small and very small processors? Or is this really something that is, in your opinion, untenable?

Trey LaPorta: It really depends on what the regulation is. If the regulation is in making salmonella in adults, how is the small processor supposed to control that? We really don't know the answer. We don't know how possible it is. And really, we want to work with whomever will work with us to meet whatever regulations exist, but we don't want to go out of business before that happens. That's all we care about. We want to stay in business and provide high quality food to our local regions.

Dr. Denise Eble...: Thank you.

Mark Williams: I want to take this time to thank everyone, the commenters, the panelists for the really, really good conversation.

Now, we'll take about a 10-minute break. When we reconvene, we'll have our third public comment period, focus on component number three. We'll see you back at 1:08. Thank you.

Sally Ann: Hello, everyone. It is now 1:09, so we are going to go ahead and move on to our next public comments period. This is Sally Ann Iverson, again. I will be moderating our next session.

We're now going to turn our attention to component three of the framework, which is implementing an enforceable final product standard. We're, again, going to hear from our attendees who have preregistered and were assigned time to provide comment on this component.

As a reminder, each commenter has been allotted two minutes to speak, so please limit your comments to that timeframe. If you're still speaking after two minutes, our event producer will let everyone know that the comments have gone over time and that we must move on to the next commenter.

We have FSIS panelists available for this comment period to ask any follow up or clarifying questions. We have Ms. Rachel Edelstein, Assistant Administrator of the Office of Policy and Program Development, Dr. Philip Bronstein, Assistant Administrator of the Office of Field Operations, Ms. Melissa Hammer, Acting Director of the Regulations Development Staff in the Office of Policy and Program Development, and Dr. Denise Eblen, Assistant Administrator in the Office of Public Health Science.

Again, we're going to follow our same format that we've been using with our commenters organized into small groups of four and time for our panelists to ask any follow up questions in between each group of commenters. When it's your group's turn, please raise your hand and Zoom, and keep it raised for the

duration of your group's time. This will ensure that the event producer can readily identify you and unmute you to give your comment or respond to any panelist questions.

We'll call on each individual intern, and you will receive a prompt to unmute that you will have to click to accept. If someone in the group is not available when we call on them, we'll move on to the next commenter in the group and return later in the group or the end of the comment period as time allows.

I will now turn it over to Dr. Eblen to give a brief overview of Component three.

Dr. Denise Eble...: Thank you, Sally, and good afternoon everybody.

For Component three, we're assessing whether certain levels or types of *Salmonella* on raw poultry product present an elevated risk of causing human illness such that they could be considered adulterants. As a result, we're considering implementing a final product standard or standards to ensure that product contaminated with salmonella that is likely to make people sick is not sold to consumers.

Sally Ann: Thank you, Dr. Eblen.

All right. We can go onto our next slide. We will get started with our first group of commenters. If you're in this group, please go ahead and raise your hand so that you can be identified. We're going to get started with Mitzi Baum. Do we see Mitsy on the line?

Tegan: I do not see Mitzi currently logged in.

Sally Ann: Okay.

Tegan: I understand that Kelly is not going to be joining us at all today, so we'll try Lam next.

Lam, go ahead and click on the popup that just appeared to acknowledge that you've been unmuted so you can speak and offer your comments.

Sally Ann: Still unable to get unmuted, I believe.

Tegan: Yeah. I haven't been able to get Lam unmuted. I understand that Mitsy was going to be speaking on behalf of Amanda Creighton, commenter four, but Mitzi is not currently logged on.

Sally Ann: Right. Let's see. We can potentially move ahead. It will be a little bit ahead, but maybe our next group of commenters, if some of them are available, maybe we can get started. We had another withdrawal in this group. We have Ashley...

Tegan: All right. Yeah, and Sarah. Let me go with Sarah. Sarah, you're commenter six. Go ahead. Be sure to identify yourself when you start your comments.

Sarah Sorscher: Hi, can you hear me?

Sally Ann: We can, yes.

Sarah Sorscher: Excellent.

Tegan: Yes, we can.

Sarah Sorscher: CSPI, Center For Science and the Public Interest, really applauds FSIS for considering Component three, implementing enforceable final product standards, which can be done by declaring *Salmonella* to be an adulterant at certain levels and for certain salmonella types; not necessarily a zero tolerance standard. CSPI has long been a proponent of taking this approach with poultry, first petitioning FSIS to consider certain strains of antibiotic resistant *Salmonella* to be adulterants more than a decade ago.

More recently, CSPI partnered with other consumer groups and victims of foodborne illness in January of 2021 in petitioning the agency to create enforceable finished product standards for salmonella in raw poultry. Then, in October of last year, we joined with other stakeholders, including members of the poultry industry, informing the Coalition for Poultry Safety Reform, which is a multi-sector group bringing together expertise from across the food chain to identify effective, practical, and science based approaches to poultry safety reform.

A key focus of this group has been identifying a smarter approach to end product standards to replace the current system of performance standards, which are not working for consumers or industry. We agree with our partners in that coalition that we're aligned in calling for standards that are objective, risk based, and achievable, enforceable, and flexible enough to adapt to emerging evidence in the latest science.

USDA now appears to adopt new standards in the framework under discussion today. While this represents a huge welcome shift in thinking by the agency. We recognize that there are a lot of important details to be worked out. We're really heartened to see the agency engaging and gathering the scientific evidence to support these risk-based standards, including consulting with the National Advisory Committee on microbiological criteria for foods, engaging in quantitative risk assessment, and expanding its sampling of products. We look forward to working with the agency alongside other stakeholders to provide feedback as this proposal is developed.

Tegan: Thank you, Sarah.

It looks like Mitzi has been able to join us, so you can go and do comments next.

Mitzi Baum: Thank you. I appreciate the time today.

Amanda Creighton, who is a constituent advocate of Stop Foodborne Illness, the organization that I represent, is not able to join today, but asked me to read her comment. I will do that prior to Stop Foodborne Illness's comments.

Amanda wanted to share... She starts by thanking everyone at FSIS for holding this meeting to discuss the problems with *Salmonella* and poultry. Your commitment to this public health issue means the world to my family. My son, Noah, was sickened during an outbreak of salmonella Heidelberg from poultry produced at Foster Farms in 2013. He was 18 months old at the time and suffered a life altering injury when the *Salmonella* attacked his brain.

I have been advocating for updated regulatory standards since my son became ill. However, I believe that enforceability is an equally essential part of protecting public health and preventing illnesses like Noah's.

During the Foster Farms outbreak in 2013, FSIS identified a specific product that was causing life threatening illnesses, but were powerless to institute a recall. The outbreak continued for 14 months, sickening and identifying a total of 634 people from 29 states. Noah became ill seven months into the outbreak in October 2013. If someone had stepped in and recalled the product after it was known to cause illness, my son would've never gotten sick.

I'd like you to know how much I appreciate your efforts in this area.

For Stop Foodborne Illness, current performance standards allow poultry contaminated with harmful salmonella to be put into commerce. This is evidenced by the CDC statistics that estimate 1.35 million illnesses are associated with salmonella. 20% of those are attributed specifically to poultry.

This equates to adulterated product receiving the USDA mark of inspection, a mark that evokes trust for consumers. This mark should be meaningful. If consumers actually understood that they are spending their hard-earned dollars on products that aren't safe, I think we'd be having a completely different conversation today.

In November 2021, Stop Foodborne Illness conducted a poll of 1000 registered voters. Those voters overwhelmingly supported stricter regulations for safer poultry. 50% of those polled said they were very much in favor of stricter poultry standards, if that meant the product that they purchased at the grocery store was safer.

We need to focus on an enforceable finished product standard that really hones in on the serotypes that are known to cause human illness. These standards must be flexible to new and evolving science.

Thank you.

Tegan: All right. Thank you, Mitzi.

We'll go on to Ashley next.

Ashley: Thank you.

NCC supports collaborative efforts to reduce *Salmonella* on finished products. We encourage FSIS to build on the successful path, establish their performance standards, whereby the industry and agency collaborated to meet voluntary standards. However, we do not believe the Poultry Products Inspection Act provides statutory authority to create a new enforceable, adulteration based final product standard for *Salmonella* in raw poultry.

There are several unresolved issues with doing so, including the necessary testing technology does not exist today. FSIS's own testing method cannot quantify *Salmonella* at a proposed level at one CFU, like it is suggested in another product class. Supply chains are not designed to test and hold raw poultry, which has a short shelf life. One sample should not be used to determine the acceptability of a lot. It is not clear what amount of testing would be necessary to truly achieve a representative and statistical value.

After scientifically determining the impact on public health, FSIS could consider a quantitative approach and give industry the opportunity to meet an enumerative performance standard. This has several benefits, including flexibility, ease of implementation, more responsiveness to existing supply chain and procurement practices, not requiring new testing technologies, and generating valuable long-term data about the amount of *Salmonella* on raw poultry.

Second, FSIS could take a risk-based approach and perform a baseline analysis to determine which chicken products may contain more *Salmonella* than others. The agency has been collecting chicken parts since January of 2012 and could have developed a significant dataset over the last 10 years.

We know that consumers prepare various chicken products differently, from chicken wings to boneless skinless breasts to ground chicken. We also know that there's a variation in the potential amount of *Salmonella* depending on the product.

Finally, FSIS could borrow on its experience with *Listeria monocytogenes* control in ready to eat products and classify establishment based on different

alternatives used to control *Salmonella* in raw poultry. This alternative ranking system could replace the current category structure.

Thank you.

Tegan: Thank you for your comments, Ashley.

We'll go ahead and go to Patricia next. Patricia, go ahead and click on the button that just popped up and go ahead and speak.

Patricia Buck: Hello, my name is Patricia Buck. I am the co-founder of the Center for Foodborne Illness Research and Prevention.

Over the past two decades, *Salmonella* contamination in USDA food products has remained a serious public health issue because the food safety system called HACCP, adopted by USDA in the late 1990s, has never been fully implemented. As you know, since the 2001 Supreme Beef versus USDA decision, FSIS has not been able to enforce its *Salmonella* end-product standard, even though salmonella has remained a pressing food safety issue.

CFI believes that component three of the proposed framework is vitally important since we think that FSIS absolutely needs the authority to enforce end-product standards in a timely manner. American consumers need and deserve better food protection from deadly and disabling salmonella infections.

CFI also recommends that FSIS hold in depth technical meetings to discuss more deeply its proposal to develop initial standards based on quantification or its idea to use documentation to ascertain the health of incoming flocks.

CFI applauds FSIS for its intention to establish *Salmonella* as an adulterant in breaded, stuffed, raw chicken products, and to identify those *Salmonella* serotypes that are most often associated with human illness.

We hope that the timeline for that proposed action is swift. Again, I thank you for the opportunity to make these comments.

Tegan: Thank you for your comments, Patricia.

Sally Ann: All right. We managed to get through two groups of commenters in that time. We do have some time for questions from any of our FSIS panelists.

Dr. Denise Eble...: Hi.

Sally Ann: Could I... Oh, go ahead.

Dr. Denise Eble...: I was just going to say, I could kick us off. Ashley had mentioned, Dr. Peterson had mentioned all the different kinds of products, many different kinds.

What are the panelists; Ashley, and other panelists; your thoughts on a product standard? Should it be the same or different, or how might we decide on this considering the variety of different chicken products that are out there? Raw chicken products.

Ashley: Dr. Eblin, can you hear me?

Dr. Denise Eble...: Yeah, I can hear you now.

Ashley: Oh, perfect.

I don't believe that a one size fits all approach is really the best move here, which is why we are thinking that perhaps doing a baseline to look at the potential salmonella load on various products would be beneficial. Again, we really support a risk-based approach to a performance standard. I think it would be really helpful to do that baseline, and then you could use some of that information in a risk assessment model to determine what products need to have more focus based off of consumption.

We know that people eat a lot of boneless skinless breasts more so than probably ground chicken, so again, just defining what risk looks like with each product would be beneficial. To put every product in the same category is probably not the best approach.

Dr. Denise Eble...: Thanks.

Thoughts by any other panelists or from any other ASR commenters?

Patricia Buck: Hi, you hear me?

Dr. Denise Eble...: I can, Patricia. Yes.

Patricia Buck: Yes, I would agree. I think we have to have different standards for different products. That's why I made the suggestion to have some in depth technical meetings so that some of those issues could be worked out.

Dr. Denise Eble...: Okay.

Rachel Edelstei...: Hi, this is Rachel. I wanted to follow up on a couple of things Ashley said.

Ashley, I was just going to ask you to elaborate a little bit. When you said, "A quantitative approach would be appropriate", because originally you said that you've got concerns about the one CFU per gram. Can you clarify what type of quantitative approach would be appropriate?

Ashley: Thank you, Rachel.

I think what we are suggesting is that the agency perform a baseline to determine what the amount of salmonella is on various products. The concern on the one CFU, and we're going to steal my thunder on the next set of comments, but the current limit of detection for the platform that the agency has selected is 10. To go below that, you use more of estimation techniques, and so we don't think that setting a standard based off of an estimate is scientifically valid.

I think it's important that we do a baseline, we use a risk assessment model and determine what our next steps are from there, but just creating a one size fits all approach for all poultry products, I don't think that's really the right way to go.

Rachel Edelstei...: Okay. Thanks for clarifying.

Can I ask one more follow up for Ashley? I'm sorry.

Also, I was interested in what you said about classifying establishments based on their interventions and their controls. Are you suggesting, once they're classified, FSIS could use different verification activities, or are you suggesting we'd actually post the classifications, or both?

Ashley: I don't really have a suggestion on that. I think what would be important is to evaluate the various establishments' food safety system, how they control poultry, and the interventions they have in place. Very similar to how the agency reviews establishments that make ready to eat products with regard to LM, and perhaps use that model and see if that may be a better approach than the current category system with a prevalence-based performance standard. Again, looking at an enumerative standard, and then perhaps more of an LM approach for *Salmonella* control.

Rachel Edelstei...: Okay, thank you.

Philip Bronstei...: I have more of an observation than a question because I think we're going to touch on it later in the crosscutting issues. I do want to state that it sounds like, on this issue in particular and in previous that we've heard, data sharing is going to be key, technical meetings and information. I think it's going to be key for everyone to be able to, if they can, identify the data sources that are important for making these sources of standards and finding a way to share them.

I won't ask a question right now, but maybe we think about that when we get to the crosscutting issues about this specifically. What are the barriers to data sharing, either from the industry side or academic side, and being able to help us define standards that would be appropriate for different types of products out there on the market?

Rachel Edelstei...: I did have one question for Sarah.

You had mentioned your support overall. I was interested in it whether you had... I'm assuming, but do you support standards that identify specific serotypes or specific levels?

Sarah Sorscher: Yeah. Thank you.

I think, like Ashley... I don't often agree with Ashley, but in this case I do think that it's really important to have that risk assessment in place to figure out what would be the most protective, the most correlated with public health outcomes. It could be a number.

In our petition, we did focus a lot on serotypes because we do feel like incentivizing those pre-harvest measures... We look to the examples of heidelberg and typhimurium and really trying to get rid of the most virulent serotypes. Getting them out of the system is important. There's a lot of good data that dose matters, so having a standard based on enumeration and getting that level below the point where it can make people sick is also a potentially really valuable approach. We have not committed one over the other.

You asked a question, also, of Ashley about, would it be better to have categories and post names? Would it be better to have different regulatory scrutiny? I would say yes to all of these things. I think it's really important for us to have that end product standard that's enforceable, that's correlated to public health so we can really have a good sense that we're getting the worst products out of the market.

We need that belt and suspenders approach. We need to be able to look at, scrutinize every step of the process, as well. I think all of the testing proposals are good if we can ensure that those tests also are aligned with that end product risk. If we can't, then I think this proposal of categories is an interesting one to explore. I think making sure that plants are using those best practices all the way through the process, and then posting their names so customers can make choices, and devoting regulatory resources towards the ones that aren't taking those steps is a good way to scrutinize that process, as well.

Sally Ann: Thanks.

All right. Thank you to our commenters. Do we have any final questions for these commenters from our panelists?

All right. If not, I think we can then go ahead and move on to our next group of commenters.

All right. Thank you. If your name appears in this group, please go ahead and raise your hand on Zoom so that we can identify and unmute you when it's your time to speak.

Tegan, do we have our first commenter online yet?

Tegan: All right. I do not see Sean Drayton on the line, but we go to Michael Hansen instead.

Michael Hansen: Thank you. Michael Hansen, Consumer Reports.

We strongly agree that FSIS should require enforceable final *Salmonella* product standards for all poultry. We also believe that the standard should be the one that tracks human *Salmonella* illnesses associated with consumption of poultry products.

As noted in our response to Component one, perhaps FSIS could consider developing a standard primarily based on their proposed KPI modified, which we have shown does track human *Salmonella* illnesses associated with chicken and turkey. Thus, we think there should be separate standards for different poultry products.

For chicken, the standards could be based on a KPI that is defined as a total number of serotypes of enteritis, infantis, and typhimurium found in a year of *Salmonella* verification testing divided by the total of positive *Salmonella* detected in that same year.

For Turkey, the KPI should be like that for chicken, except the three serotypes should be reading, infantis, and typhimurium. Enteritidis isn't found in Turkey.

Basically, the KPI is a percentage of all positive *Salmonella* samples that are made up of the three specific *Salmonella* serotypes. Our analysis of the FSI is salmonella verification sampling program data from 26 to 2019 shows that, for chicken, the KPI increases from 41% to 50%, clearly showing that the three serotypes were a significant fraction of all *Salmonella* detected in chicken.

For Turkey, the KPI goes from 25% to 43%, showing that reading, infantis, and typhimurium are a good percentage of all the *Salmonella* detected in Turkey.

Since we know that the proposed KPI, especially for chicken, does track human *Salmonella* illnesses associated with consumption of chicken products, perhaps FSIS could consider setting a standard for chicken that starts with the standard of, say, 50% of salmonella samples coming from a plant, and then requiring that number to decrease by a certain percentage every year.

Since the KPI was 50% for 2019, FSIS has already proposed having the KPI decrease by 1 to 2% per year for the next five years. Perhaps, they could consider having the KPI standard decrease by more than 2% per year.

Thank you.

Tegan: Thank you, Michael.

We'll go to our next speaker on the list. That would be James McNaughton.

James McNaughto...: Thank you.

I'd just like to make a comment related to Ashley's comment earlier, and that has to do with prepackaging and the proposed regulation of one CFU per gram of meat.

That is a low number to detect. I understand that, but it also exposes the *Salmonella* has much less biofilm around it and is easier to kill. Moving salmonella incidents, which I've never liked, post-kill, very difficult to measure, very difficult to test different measures of controlling it. You've got to run that plant for weeks before you really get a measure on it; whether something's working or not working.

We actually, in our test, measure those numbers by different treatments. We measure those numbers per gram of feces and then per gram of product at the end to see whether something is working or not.

The second point I'd like to make is that, eventually, the consumer is going to need to have a little package with a disinfectant in it that they wash their veggies in, which is certainly related to lettuce, as well as deli meat or whatever they open, and eventually take that responsibility. I'm not talking sharing or transforming the legal ramifications from the integrator, but certainly giving that customer a choice of controlling its own destiny.

That makes up my comments. Thanks.

Tegan: Thank you, James.

We're going to go ahead and go to Katie Rose McCullough next.

Katie Rose McCu...: Good afternoon. I am Katie Rose McCullough, Director of Science and Public Health at the North American Meat Institute.

Consumers health and safety are the driving forces for our members, packers and processors of the meat and poultry products. *Salmonella* has been and will continue to be a high priority for the meat and poultry industry. Our industry is committed to protecting consumers and continues to invest significant resources to fund research targeting critical aspects of food safety to improve public health.

The Meat Institute commends the agency for their effort to reduce the burden of salmonella illnesses attributed to poultry products. The proposed framework is an innovative approach to meet the healthy people goals. However, while the

approach may be innovative, it lacks practical data demonstrating its effectiveness.

Prior to releasing new regulations, the agency should pilot these approaches or collect more data demonstrating the effectiveness prior to making them in industry requirement.

Each component has gaps in practical information, especially related to sample collection methodology. Each component requires additional testing without providing key information the industry needs to consider the application in their processes.

Some of the sampling requirements of these components are currently methodologically impossible with the testing resources available today. These details must be finalized before any framework is finalized. Specifically related to Component three on final finished product testing, before updating and changing the finished product testing standards, the agency needs to give ample time for attribution information to be collected and analyzed to determine if the approach will have the desired public health outcome.

Furthermore, you cannot test your way to food safety. Finished product testing is a valuable verification tool, but the agency should not place too much emphasis on final product testing. The industry needs to maintain its focus on aggressively targeting salmonella. The Meat Institute supports regulatory programs that are science best, data driven, practical, and improve public health.

We look forward to continuing to work with the agency on our mutual goal of providing safe meat and poultry products to consumers. Thank you.

Tegan: Thank you, Katie Rose.

Sally Ann: Thank you.

All right, Tegan. Has commenter nine come online yet, or still no sign?

Tegan: I have not seen commenter nine join yet.

Sally Ann: Okay. All right.

With that, we will have some time for any questions-

Sally Ann Ivers...: With that, we will have some time for any questions or comments from our FSIS panelists.

Rachel Edelstei...: Hi, this is Rachel.

Philip Bronstei...: I have one.

Rachel Edelstei...: Oh, go ahead, Phil.

Philip Bronstei...: All right. I have a question for Michael Hansen. In listening to what you were saying, it sounds like you're asking more of a performance standard than a final product standard. Would that be in addition, do you think, that we would need a performance standard where we are looking at a level over time that reduced and a final product standard or do you think [inaudible 03:18:45] better than a final product?

Michael Hansen: Whichever gets a reduction in illnesses I think is what works. We're fine having it as... Maybe you make it a performance standard. You could change it depending on a product type, but it should be required to decrease every year. Again, you should be always tracking how that KPI or what we're proposing, how that compares to the IFSAC because you want to see those going down.

If you make it a performance standard and then you say it can't be above that and then set levels where you want to put them in categories so that you then post that information and drive it down that way, fine, but I think the bottom line for us is that particular standard that we suggest coming up with, since it is linked to human illnesses, you should find a way to make sure that that's going down over time. If you want to do it as a performance standard or as required one that moves, that's fine. It's just whatever works to get it to decline over time with penalties if it doesn't.

Philip Bronstei...: Understood. Thanks, Michael.

Rachel Edelstei...: I had a question about that too. Just to follow up and you can see in our framework, we were trying to come up with final product standards that would be more enforceable than the performance standards. If the standard applies to that finished product and that product is adulterated, it can't move into commerce and that's where... We don't get there with the performance standard approach.

Michael Hansen: Well, the that's true but I guess part of our thought on that is the time it's going to take to develop a standard that is risk based that you say will consider stereotypes and for example, virulence levels or quantities, to gather all that data and show that they are actually tracking something, that is going to take forever or that's going to take at least a year. What we were thinking is since we have something that appears to be working and FSIS has already said that they want to focus on these ones, fine.

Try that and see if we can get something implemented quickly to have that go down. I don't have any problem with developing this final product standard. The only concern that we would have is the data you would need to back that up in terms of showing that particular serotype or particular levels that on a product

are ultimately linked to illness. That seems to me that's going to take quite a while. We were just trying to think of something that could be doable in a shorter period of time while you're developing the data for the longer...

Rachel Edelstei...: Thanks.

Dr. Denise Eble...: I guess my comment builds on that too. Ideally, we do want to have a flexible structure to set finished product standards. As science evolves and time moves on, how might we do this? Because we know that what we do will have a big impact on the whole field. Any suggestions on... Any thoughts from the commenters on what we need to be mindful of as we consider not just setting the first potential standard but updating it subsequent to that?

Michael Hansen: Yeah, I'll say something. Again, this is Michael Hansen. What I think might be useful is since it does look, just from our looking from the past data for chicken, those three serotypes really are dominating overall, and then in our testing of brown chicken, that appeared to be the case as well. Since FSIS does have all this data, they could look themselves and just make sure if other stereotypes are coming up so that the top three change or the top five change, then you should change with them, but seeing that these three have gone up from 40 to 50% in chicken does suggest that they're going to be the major ones.

But yes, you should always be watching that so that if the top three or the top five, if there are other ones that make a greater percentage than that, then yes, you should switch over to them, because what might happen is you might drive these down and illnesses from those go down and new ones come in. You should always be looking at your serotype ratios, because you're always going to have that from your verification testing. And then as the IFSAC data comes up every year, again, you want to make sure to see if that's tracking as well as it did from 2016 to 2019. Does that make sense?

Dr. Denise Eble...: Absolutely. Absolutely.

Katie Rose McCu...: I would like to-

Dr. Denise Eble...: Go ahead, Katie Rose.

Katie Rose McCu...: Oh thank you, Dr. Eblen. I would like to build on that a little bit because the data is, I think, going to be a key piece here, because we may have three serotypes that we can focus on this as major illness contributing stereotypes, obviously, probably something even more specific than serotype would be ideal in a perfect world. I don't know if we're there yet with the science, but you go back six, seven years and there are different serotypes, and so, I think a fast turnaround of the data I think is going to be key and I think it's going to be key to have these discussions with the public health partners over at CDC because again, with a moving target, it's going to be something that's extremely challenging for industry to meet when it comes to any final product standard.

I'm not saying it's not right because we know things are going to change. We know salmonella's complex is going to change, but if we're not matching that to know why or we did or did not see a reduction in illness, we're going to end up in the same place 5, 10 years from now, because again, I point back to performance standards did drive down... And the agent has said this... Did drive down *Salmonella* in poultry products, but we didn't see that result in the consumer data. Until we can really understand that difference, I think sometimes a finished product standard being a moving target can sometimes almost be more trouble than it's worth because again, why are we not seeing what we should? Until that relationship is better understood, it's going to be really difficult to come up with a final product standard that everybody's got a lot of confidence in.

Rachel Edelstei...: Yeah, I wanted to follow up on that because Katie Rose, you mentioned that before, that you didn't think the finished product standard is appropriate in this and for poultry. We've had a lot of success with the finished product testing for beef. Is that why you think it's not appropriate for poultry just because of the... That we're not able to see the reduction in illness that goes with the reduction at the plant level?

Katie Rose McCu...: Thank you, Rachel, for asking questions because I definitely want to clarify. I don't want to give the impression that we don't think there is no role for finished product testing, that we should do it with it completely. I just want us to be leery of changing that often and upping and putting a lot of emphasis on that because of that disconnect and because again, we know we cannot test to assure food safety. It's not like we can say, "Oh, we tested this and it's statistically valid so we can assure this lot or this combo of product is safe or *Salmonella* free." We're never going to be able to get there.

It is meant to be a verification of other food safety processes, and so, I just worry about us putting too much faith and emphasis in what a finished product test is going to be able to tell us, but that doesn't mean there isn't a place for finished product testing. Yes, part of it is what you alluded to. We didn't see what we saw with beef... But it did take us years to see the reduction of illnesses in beef after the changes made in the nineties, and so, I think that's an important component for us to understand when we're trying to compare product samples and finished product testing versus what we're seeing with attribution. Like I said, I just think we need to be careful on where we place this emphasis and where the agency places a lot of its resources moving forward.

Rachel Edelstei...: Thank you, and then James had also mentioned concerns about the finished product testing. Was it along the same lines or did you have additional concerns just about... You had mentioned maybe there's more value in the PCs product testing pairs.

Sally Ann Ivers...: Are we able to get James unmuted?

James McNaughto...: Okay, I got it now. Yeah. I take it from the standpoint of how do you test products that might be reducing *Salmonella*, both in finished products as well as post-chill, and if you put it on a per gram basis, whether it be meat or fecal, whatever, it may or may not work as I actually said with these quick tests, but it certainly is a way to define measures that will or will not work long term, and there're exciting products coming out, phages being... Some of those that will be used in prepackaging, because it's so expensive, and so, it's an important item to me to be able to relate the control measure to what actually works in reducing it if that makes any sense.

Rachel Edelstei...: Thank you.

Sally Ann Ivers...: Right. Any final questions? [inaudible 03:30:03]. Okay, then thank you to our commenters in this group for providing your feedback. We can go ahead and advance to the next slide. All right. Again, if you're listed in this group, if you want to go ahead and raise your hand and we will call on you when it's your time to unmute.

Tegan: All right. We'll go to the first commenter on the list. Daniel, go ahead. Don't forget to introduce yourself before you begin your comments.

Daniel Glucksma...: Okay, great. You can hear me okay?

Tegan: Yes, we can.

Daniel Glucksma...: Okay. My name is Dan Glucksman and I'm the senior director for policy at the International Safety Equipment Association, which is the association for companies that design, test, manufacture and supply a wide range of personal protective equipment. ISE asks that USDA include in the framework and any related rule making worker safety measures. These include use of a fit-tested YF certified respirator.

The use of respirators could also prevent avian flu exposures while people are conducting flock inspections for *Salmonella*. ISE asks that workers also use nitrile gloves, which will go a long way to preventing punctures, and finally, that new clean disposable garments should be provided at no cost to the worker each time an inspection takes place, and we'll also submit these comments in writing. Thank you for the opportunity to comment.

Tegan: All right, thank you Daniel. We'll see if Devendra has joined us. Nope, not yet. We'll go ahead and go next to Chelsie Romberger. Chelsie, go ahead.

Chelsie Romberg...: Hello. Thank you again. Chelsie Romberger from Bell & Evans. The comment in the proposed framework that FSIS could also take into account documentation presented with a flock and make a regulatory distinction between vaccinated flocks and non-vaccinated flocks, in the context of a final product standard,

indicates that FSIS has evidence to demonstrate that vaccines are the most effective pre-harvest intervention in the control of *Salmonella*.

However, just like in an establishment, a multiple hurdle approach is the most effective way to control for *Salmonella*. If FSIS is willing to take into account pre-harvest interventions such as vaccines in the context of a final product standard, would they also take into account other pre-harvest intervention types such as competitive exclusions, probiotics or prebiotics in the feed or organic acids in the drinking water.

Would FSIS also make a distinction between different vaccine types comparing the effects of live attenuated vaccines versus autogenous vaccines or vaccines used in pullet and breeders versus broiler vaccines? We're asking that FSIS take into account the use of pre-harvest interventions other than vaccines in the context of a final product standard so that a cumulative pre-harvest intervention strategy is factored into the regulatory distinction of a final product standard. Thank you.

Tegan: All right, thank you for your comments Chelsie. We'll go ahead and see if Rafael has joined us, and Rafael Souza has not. I will turn it back over to our moderator.

Sally Ann Ivers...: Okay, thank you. Do we have any questions from our panelists for any of our commenters?

Dr. Denise Eble...: I can start. Chelsie, thanks for your comments and thanks to all of you, but I have a question for Chelsie. You talk about the possibility of us putting in finished product standards that have distinctions based on the pre-harvest interventions, whether it be vaccines or other things, but is there any information out there to show that there really are interventions that work all the time?

The data that I've seen so far that I'm aware of seems to show that some things work in some cases, but they're not necessarily reproducible across time and places. What are your thoughts on that? You mentioned a lot of things like competitive exclusion, prebiotics, probiotics, acidified water and so on. Are you confident though that the application of these is uniform enough that it really would carry through to the finished product?

Chelsie Romberg...: Thanks, Dr. Eblen. I think I can speak for most commenters here that none of the interventions would work all the time for all cases, but really, what we see throughout industry is that a multiple hurdle approach is the most effective. One or all interventions used differently may have different effects at different times, factoring in considerations like seasonality, geographic locations, flock age and all of that.

The agency didn't really provide a lot of context on how they would consider the regulatory distinction between vaccinated flocks and non-vaccinated flocks. The point that we were hoping to make with this comment is that vaccines are certainly a great tool in the toolkit for pre-harvest interventions for the control of *Salmonella*, but they're not the end all, be all.

Dr. Denise Eble...: Good point. Thank you. Thanks for clarifying.

Speaker 15: [foreign language 03:36:00].

Sally Ann Ivers...: Looks like we have... There we go. Any other questions for commenters from our FSIS folks? Rachel, go ahead.

Rachel Edelstei...: I was just going to clarify in the component three when we were talking about how we might treat the establishments differently, one thing we were talking about is just internally, maybe just our verification could be different or verification activities could be different depending on vaccinations or use of vaccinations or other interventions, but we'd definitely be interested in your feedback on how the standards could be different or how our verification activities could be different.

Philip Bronstei...: Yeah, correct. That goes back to... I think it was Ashley who brought it up or maybe [inaudible 03:36:57] or Katie Rose, I can't remember, but maybe akin to the Listeria categories.

Sally Ann Ivers...: All right. Thank you. Any other questions on the FSIS side? All right. Then with that, we can go ahead and move on to our next group of commenters so we can advance the slide. Okay. If you're in this group, please go ahead and raise your hand.

Tegan: All right. We'll go and see online. All right, let's go to Michael Hogan, who's first on our list.

Michael Hogan: Oh, thank you very much. Can you hear me?

Tegan: Yes, I can.

Michael Hogan: Okay, great. We've sent over a reasonably detailed response again, and in this case I'll just go over and summarize it a bit. We're very excited and think it makes very good sense, this idea of focusing in on explicit analysis of serovars as part of the safety process. However, the one concern we have is that the initial focus, for good reasons in a practical sense I guess, as cited is to consider really only looking for three principle serovars as part of the initial regulatory framework and perhaps pilot testing, and all we wanted to point out is the obvious. It has been discussed earlier today that number one, even in chicken, those three serovars comprise perhaps a little bit less than half the disease seen and generally speaking, then those numbers are a little soft and more generally,

only constitute about 30% of all the *Salmonella* disease that is known per the CDC.

The take home message is that we've come into this as a company. We know that expanding the scope broadly to include quite a few more serovars can be done at scale and can be done at the one CFU limit. We come into the business doing nucleic acid testing in other markets, cannabis and so forth, which already have one CFU per gram detection limits, and we have numerous AOAC-approved PTMs that demonstrate this. I think it's not pie in the sky to say that one should be and can be deploying nucleic acid-based tests that can do serovar testing at scale throughout the supply chain at a cost that's very similar or perhaps a bit less than plate culture-based methods and do so soon-

Tegan: All right. Sorry to interrupt, Michael, but your two minutes have ended, so we're going to go ahead to the next person. All right, Thomas, it's your turn.

Thomas Gremilli...: I'm just going to go ahead and start. Assume you hear me. Thomas Gremillion from Consumer Federation of America. Component three for us is the most important component of this framework. Enforceable final product standards are the keystone to an effective FSIS regulatory strategy for *Salmonella* and poultry. Enforceable standards are only possible, however, if FSIS declares *Salmonella* an adulterant in raw chicken products. Fortunately, the law supports declaring *Salmonella* an adulterant.

There's no question that high levels of *Salmonella* serotypes associated with human illness; enteritidis, typhimurium and infantis, others, high levels of those stereotypes may render or even ordinarily render a raw chicken product injurious to health. The issue for FSIS is where to draw the line. One possibility is that the agency test final product samples against multiple standards and high enough levels since high enough levels of virtually any *Salmonella* pose an unacceptable risk to consumers. You could have a quantification-based salmonella species standard and at the same time, have serotype specific standards that provide that incentive to eradicate the most dangerous *Salmonella* further up the supply chain.

FSIS could set the permissible threshold for these serotypes at a lower level, if not zero. Similar to how FSIS varies the frequency with which it conducts *Listeria* verification testing, as others mentioned, you could vary that verification testing against *Salmonella* standards and take into account things like vaccination status, but also all of the things that are in the FSIS pre-harvest guidance. One last idea I want to put out there in setting any enumeration-based standards, there's often reference to an infectious dose for healthy individuals, but it's a lower infectious dose for high-risk individuals and the standards should take that into account. Thank you.

Tegan: And your two minutes is now up. Sorry to interrupt, we're going to go to Art next. Art, please go ahead.

Art Lona: Yes. In the discussions we're hearing, I'm hearing a lot of information on the testing and we have the device that we feel can improve the product and protect consumers. We feel that providing a more effective method of decontamination, it will be possible to reduce the need for additional costly regulations while at the same time, provide safe products. By reducing or eliminating the threat of *salmonella* during processing, this will help all processors. Very small as well as the large processors.

Now, we do believe in and support testing, especially as it pertains to improving the quality of the consumer product. We welcome anyone interested in participating with further development and ongoing testing to reach out. We are able and willing to dedicate the resource to determine how pulsed UV light can start to be integrated into the regulatory frameworks, and we understand that it's a new approach to microbial decontamination. We appreciate the opportunity and we appreciate FSIS holding this forum for us to participate and hear other folks' perspective as well. Thank you.

Tegan: All right, thank you, Art. I've been made aware that commenter 20 has withdrawn, so I'll turn things back to our moderator.

Sally Ann Ivers...: Thank you, Tegan. All right, so we again have time for any questions from our FSIS panelists. Rachel, would you like to...

Rachel Edelstei...: Yeah, Thomas, could you clarify. I wanted to make sure I understood what you were recommending. Were you saying we would identify certain serovars that would be considered adulterants and then have different levels depending on the serovar?

Thomas Gremilli...: I was looking at the component that says, "Levels and/or stereotypes," and I'm thinking, why not both? You could have a standard that says, "If you've got this level of salmonella overall, X CFU per gram or whatever, then that's adulterated," and then have a lower... If you've got Y units per gram of this particular serotype, then that's also adulterated. One idea. Does that make sense?

Rachel Edelstei...: Yeah, I see what you're saying now. Yeah, thank you. Honestly, I don't know if that makes sense for how we test, but thanks for clarifying.

Thomas Gremilli...: Sure.

Sally Ann Ivers...: All right. Any additional questions on FSIS side?

Philip Bronstei...: Well, I just have a general question and comment. I think we've had a lot of really great comments on component three in general, but I didn't hear a whole lot barring Thomas's on levels on enumeration versus presence minus and that aspect. If anybody wanted to comment further on that or if on written comments later, I think that would be appreciated from the agency on what are

the different things that we should consider, because I do agree with Thomas that that infectious dose can be tricky and you're not just talking about infectious dose. You're talking about the concentration of *Salmonella* at a particular point in a process, whereby FSIS regulation chiefly is at the slaughter and processing facility and outside of that door, a lot of things can happen to that product.

Whether that's transportation to the point of sale, whatever happens at the store where the product is being sold and then whatever happens between selling that product and how the consumer handles it all the way through cooking of that product. It's no small task to try to understand exactly what should be the most protective level or the most effective level shall we say, that we should create while trying to balance having clinical safe food as well as reducing the number of illness-causing servings out there on the market. Thomas, I talked a little bit. Maybe you have a few more thoughts about that.

Thomas Gremilli...: Yeah, I think it's an interesting problem. I just mentioned having a *Salmonella* species standard, but you could have tiers of... Have your three serotypes that have been identified in the key performance indicators set with one standard and then have a heidelberg and the other stereotypes of concern set to a secondary standard and be moving them if heidelberg jumps up into the top three, that it could move from the second tier to the first tier and whatever threshold that's set in the enumeration standard could apply.

I am nervous. The enumeration concept makes me a little nervous because if it could be set too high. We've seen with campylobacter, you essentially had enumeration or a high quantitative threshold and it didn't seem to be meaningful and the agency had to scrap it. It has to be set low enough to provide an incentive for mitigation, but I think it gives you a lot of flexibility.

Sally Ann Ivers...: Thanks, Thomas. I think there was some interest actually in even opening up the question that Phil just posed. If any of our commenters who had preregistered for component three would like to respond to that, you can go ahead and raise your hand. I think I see Katie Rose's hand raised.

Katie Rose McCu...: Thank you for the question, Dr. Bronstein. This is Katie Rose McCullough with the Meat Institute and I think the level approach is something that the industry has been doing and been looking at privately and I think that it shows that it has been effective it in a lot of ways. I think it certainly makes some sense to look at more of a level-based approach, because we know that virulence changes with *Salmonella* and not all *Salmonella* are created equal. If we all had a nickel for every time we heard that, we would all be able to fund a lot of *Salmonella* research, but something that has relatively low virulence and holding it to a prevalence-based standard is not going to improve public health, and so, how do we really find the ones that are posing the greatest risk, understanding the complications with-

Katie Rose McCu...: ... The greatest risk understanding the complications with infectious dose, and I think that's why components for any finished products testing is only one aspect of this whole story. There is other parts of this that are important in the food safety story, including what happens after the plant and how that product is handled, as was hinted at and mentioned by the retailers and grocery stores and even by the consumers, how they're handling that, and that's an important part of this whole overall story that we're doing. So I certainly think a level-based approach is what the agency is thinking about is the appropriate thing to be considering.

I think we just need more FSIS data, practical data to show that it is something really worth holding everybody a standard to because again, there are complications with finished product testing standards when it comes to a product with a short shelf life that I don't think we've really brought up enough in this conversation. We've brought up a lot of things that would be theoretically wonderful if possible, but we're not there with the testing technologies and I know the agency has said over and over again, "The testing companies will build it, the testing companies will build it." They've been working on it and they will still continue to work on it.

And we tell them, but those things definitely don't happen overnight and the validations to get those tests to where we have confidence in those tests don't happen overnight, and so I think a lot of that needs to be brought up and taken into consideration when we talk about any change in the finished product testing, whether it's level-based, or it's a serotype, surveillance-based, or whether it's a combination of all of those, which we know in a perfect world, that's probably where we would want to be, but we're not there yet and it's really going to take us, unfortunately, years to get that from a testing methodology perspective.

Sally Ann: Okay. Thank you, Katie Rose. I think we had a couple other hands up. Ashley?

Ashley: Yeah. Great question, Dr. Brownstein, and I will agree with Dr. McCullough. I think that we definitely need more data, which is why we're thinking that perhaps the best approach would be for the agency to perform a baseline analysis for the various chickens to determine risk. There is a shelf life concern with product. Obviously, we're in the fresh meat business and shelf life has to be considered, but I also agree with Katie Rose and her comments on the limits of testing.

And that's why I think one of the concerns on looking at serotype specific standards is that there is a limit or the timed results is a significant limiting factor for the industry today, but I do think that again, a baseline and then following that up with a risk assessment to determine what products the agency should focus on, determining what concentration or what level that enumerative standard should focus on, no different than the agency has done in the past with performance standards when they do a baseline and then they factor in healthy people 2020, 2030 goals and set standards that way, and that's

a very scientific approach to moving forward. So just some other thoughts for the agency to consider.

Sally Ann: Thanks, Ashley. And I think we had Michael.

Michael Hogan: Yes, can you hear me?

Sally Ann: We can. Yes.

Michael Hogan: Yeah, yeah. Good. I agree with most everything that's been said. I just want to point out that we've gotten feedback very similar to this from folks that we've been working with from the FDA and also the other elements of the USDA and in academia at the University of Georgia, and they gave us the guidance that would be very handy to develop a test that could quantify *Salmonella* species, SPP, and to basically subtype into serovars among, let's say the serovars of concern, sort of the top seven on the CDC list and so forth, and if it would be... That's in progress, it's been in progress for, we started it and hope to have that completed soon.

So, if it would be any interest, we'd be happy to send over a little information about what's in progress and the source of the feedback to which we're responding from the FDA and USDA and academia and so forth, and see if there would be some interest. We would love the idea if it ever came to it to be involved in pilot studies that FSIS would initiate to see if in fact, this kind of information would be useful to monitor total *Salmonella* load and also serotype somewhat more broadly and more quickly than is being done right now. So, we'd be happy to send over anything if there would be some utility.

Sally Ann: Thanks, Michael. And I think we also had a hand from Pat [inaudible 03:56:29] again. You're unmuted.

Pat: Hello. Yes, in listening to all the dialogue here this afternoon, I come back to the main point, which is the end-product standards are crucial if we're going to finally end up reducing *Salmonella* in this country. I am certainly in agreement with Thomas about the idea that standards could be put together for development of different, how would you put it, programs or goals that are needed to be met to reduce *Salmonella* within the incoming flocks and within the processing plants. I think that's a very, those are temporary, but they're very, very much needed because as Michael Hanson pointed out, we need to be swift in putting something together and I encourage the agency to look at those.

I also agree with Chelsea that a multi hurdle approach is very important, and again, I encourage FSIS to move forward in that direction. Michael Hogan made a very good comment about the need to include more than the three leading serovars, and I think that needs to be investigated. Just running through the things that I've listened to and I find important, we can't get into the details so much this afternoon about how to implement all of them. So again, I

recommend that you hold some technical meetings to give more investigation. Finally, I think FSIS should think about incentives that would help to put in place some of these really important and interesting programs. Thank you.

Dr. Denise Eble...: Thanks, Pat. I have a question too. So as we've talked for all the commenters, test and hold. So if we're to do a final product standard and it takes some time to get the result back, right now, there's no instantaneous or real time test, what are the concerns about test and hold? Also, what are the concerns and thoughts about allotting practices for a finished product standard like this? Any comments on any of that?

Ashley: Dr. Eblen, I'll start, if you don't mind. I think one of the biggest limiting factors that we have discussed so far is time to results and lab capacity. So I'm going to talk about that in the next set, but I do think we're going to have limitations on lab capacity, time to results. We're not set up to store product. Product moves through the system very promptly and gets out to grocery stores or wherever it's headed quickly. From the time the birds come in until they leave the plant, we're talking hours. So I think that's one of the biggest concern on test and hold, and then lauding in the chicken space is a different challenge than it is in the red meat side. So I don't know that we've fully got our arms around how we would do a lot, but those are just some of the things that we've been talking about internally.

Sally Ann: Thanks, Ashley. I know we have a few others with hands up still that were in our last group so I'm not sure if any of those are new. Go ahead, Thomas.

Thomas: I'll chime in, just makes some obvious points about how test and hold really correlated with some you important public health gains in the context of *E.coli* with 157:H7. I'd like to hear from people with more familiarity about the testing. It seems like the testing has come a long way and that I am skeptical that it's going to be such a time-consuming process that the industry won't be able to respond to that, but yeah, I think test and hold, we've seen is really important and on the meat beef context. Thanks.

Sally Ann: Thank you, Thomas. Right. So I'm just checking for any final hands or anyone who would like to respond to that. Katie Rose, I'm not sure. I thought I saw a hand go up briefly.

Katie Rose McCu...: No, I didn't raise my hand. I think some of the comments that Dr. Peterson made were, I think really good for consideration and I think there's a place for test and hold in the industry, especially when you know it takes one very few cells to make somebody sick. We're not necessarily there with something like salmonella. Again, we got to keep in mind when we try to compare the story of what happened in beef and O157:H7 and even the other six, that we're talking about seven different things there. In *Salmonella*, we're talking about over 2,500 different things. So it's really hard to translate that story across species lines. I appreciate the creative thinking and the tremendous work that was done by the beef industry to do what they did, but this is a whole different beast.

Sally Ann: Okay, thank you. And then I just want to do one more check. Michael Hogan, if you had comments here just because I-

Michael Hogan: Sure. Just responding to the whole test and hold part. Yeah, the fact is the case that the testing with respect to salmonella load and serovars has increased, the speed has increased greatly. So I think in now actually, and in other industries, the rate limit for getting data is how long it takes to send the sample to wherever it's going to be tested, and so the fact is if it's being done at or close to the processing facility, all the data that we're talking about is easily obtainable within a shift or less. So really, I think very quickly, it's going to be logistics more than anything else and that is these kinds of tests to generate the sort of data that you want. If they would be done rather than shipping overnight to another state, could be done a little bit closer to the processing facility. That shipping time is actually going to be the rate limiting step going forward. So one needs to think about that, I think.

Sally Ann: All right. Thank you, Michael, and thank you to all of our commenters who spoke about this component. I think we had some great discussion. Again, thanks to our FSIS panelists as well. I think we will go ahead and move forward to our final public comment period for those that are preregistered. I am going to hand it over to Mr. Robert Witte who will be serving as your moderator for this next session.

Robert Witte: Perfect. Thanks, Sally Ann. My name is Robert Witte and I'll be moderating this next public comment, which will focus on the cross-cutting issues that were described within the framework. So that is testing for *Salmonella*, data sharing, and alternatives for small and very small establishments. So same as other sessions, we'll hear from attendees who pre-registered and were assigned time to provide comment on this component. As a reminder, each commenter will be allotted two minutes to speak, so please limit your comments to two minutes. If you are still speaking after two minutes, our event producer will let everyone know the comments have gone over time and that we must move on to the next commenter.

For this comment, we'll have all of our previous FSIS panelists available. So that includes Dr. Kis Robertson Hale, Chief Public Health Veterinarian and Deputy Assistant Administrator to the Office of Public Health Science, Ms. April Regonlinski, Deputy Assistant Administrator for the Office of Policy and Program Development, Mr. Todd Reed, FSIS Chief Operating Officer, Dr. Hany Sidrak, Deputy Assistant Administrator for the Office of Field Operations, Dr. Denise Eblen, Assistant Administrator for the Office of Public Health Science, Dr. Phil Bronstein, Assistant Administrator for the Office of Field Operations, Ms. Mary Porretta, Program Analyst for the Office of Policy and Program Development, Ms. Rachel Edelstein, Assistant Administrator for the Office of Policy and Program Development, and Ms. Melissa Hammar, Acting Director of Regulation Development Staff in the Office of Policy and Program Development.

So we'll follow the same format for this public comment period with our commenters organized into small groups of four with time for our FSIS panelists to ask any follow up questions in between each group of commenters. When it's your group's turn, please raise your hand in Zoom and keep it raised for the duration of your group's time. This will ensure that the event producer can readily identify and unmute you to provide your comment or respond to a panelist question. We'll call on each individual in turn and you'll receive a prompt to unmute. If someone in the group is not available when we call on them, we'll move on to the next commenter in the group and come back to them later in the group or at the end of the comment period as time allows. So with that, now I'll turn it over to Dr. Denise Eblen to introduce two of the crosscutting issues.

Dr. Denise Eble...: Good afternoon again. So as we looked over the whole framework, we realized that there are some crosscutting issues that we also want input on. So the first one is testing for *Salmonella*. So as we transition from using presence based tests to those that quantify the amount of salmonella, we've done this because we believe more highly contaminated product is more likely to cause human illness. At FSIS, we are considering targeting the serotypes of *Salmonella* found in poultry that are more likely to cause human illness, and as the science and testing technology evolves to reliably identify serotypes and pathogen factors, we hope we expect to revise our testing requirements and as appropriate, update the final product standards to incorporate these developments.

So we've touched on this a little already previously, but we'd like to have further conversation on this, and then the next point I wanted to raise was data sharing. So in addition to the current requirement of establishments, making sampling data available to FSIS in-plant personnel for review, we are considering developing a process for establishments that perform their own sampling and testing for *Salmonella* and indicator organisms of rehang and post chill to regularly share this data with FSIS electronically under the new system. So both of those are things that we'd really like to have further discussion on this afternoon. Phil?

Phillip Bronste...: Yeah, sure, thanks a lot.

Robert Witte: Let's see if we can go back. There we go.

Phillip Bronste...: All right. So the other one is we've already heard several times during our comments today, but I think it's one that we always have to be aware of is that as an agency, we are regulating all of the industry, big and small and very small throughout the nation. So we really are looking to understand what's the best way to develop policies which are going to be effective towards large establishments and in small and very small establishments. So we were interested in understanding how to help alleviate the resource burden on small and very small establishments, and so we're considering on how to account for production volume and other options as appropriate to factor establishment size into our proposal.

Robert Witte: Perfect. Next slide. So thanks, Phil. We'll now get started with our first group of commenters. Again, please raise your hand. We'll start with Andrew.

Sally Ann: All right. Let's see if Andrew is on with us. Looks like I don't see Andrew logged in, so we'll go to Claire then. Claire, go ahead.

Claire: Great. Can you hear me?

Sally Ann: Yes, we can.

Claire: Okay, great. My name is Claire Nera and I'm from the University of Maryland, and I'm speaking as the project lead on a collaborative project we already have with FSIS, we have structured partnerships in the private industry organizations, and we're really committed to working with ways to share data to better inform analysis and support policies direct to improving public health outcomes associated with upcoming risk assessments and the new goals to share additional data. We recognize FSIS as moving away from the traditional approach to conducting pathogen risk assessment to focus on *Salmonella* serovars to better target interventions to those serovars that have the greatest public health impact.

And to do this, as we've been saying and hearing from other speakers, data is needed. However, collecting data can be resource intensive and we know that both the public and private sector data collect a lot of data, but neither knows what the other has and has access to that data and how it might be used collectively to inform analysis aimed at improving public health outcomes. The benefit of being able to share that is that they will be able then to target additional data collection efforts, so we think this is really important. We believe the data sharing initiatives needed that is more than a one -event and we see that a lot of effort going through that.

So we're really happy to see that and we want to make sure that it benefits both sectors, that they recognize the benefits of the data that both sectors have with the goal, shared goal of improving public health, and we believe this can be done with the partnership with really the goal of sharing data to improve these public health outcomes. If one partners understand the benefit of sharing data amongst themself and understanding, the benefits is two ways.

Data sharing, I hear that coming in what I've been hearing, that they're willing to find these solutions to overcome these data trust concerns, they agree that data is needed and understand what is already been collected and we to share in a trusted, blinded manner, and that partners also recognize that if they go about collecting, they go about the effort of gaining a way to share that data and spend additional resources that data will be used, and to this end, we have been working with FSIS as their collaborators in this project and with the industry organizations working to form trust. And-

Sally Ann: Sorry to interrupt, Claire, but we've gone over your two minutes, so we'll go ahead and go to Sarah next. Sarah, go ahead.

Sarah Sorscher: Yeah, I think, I thought I was signing up for a general comments, so I don't have anything specific to the questions posed, but I just wanted to take this opportunity to address one thread that's been happening throughout the day, this conversation around why do we need a new approach? Aren't consumers doing just fine cooking the products, and I think I just want to say consumers are not doing just fine. More than a million of us are getting sick a year from salmonella and more than 25,000 are going to the hospital and some of us are ending up dead, and I think consumers aren't fine with that and companies shouldn't be fine with it either. They shouldn't be okay with putting out product that's making people sick and killing people.

And I think a lot of the comments today are focused on why this or that approach isn't going to work and I just want to focus on the fact that the current performance standards that we have aren't working either because they're not addressing the highest risk products and companies are rising to the occasion. They're meeting those standards, and yet what they're doing is really doing a great job controlling *Salmonella* kentucky and we see two goals. We have the regulatory goal of meeting the performance standard and then we have companies that want to actually not make their customers sick, are essentially aiming at a different target.

And trying to get the highest risk products out of commerce to protect their brand, to protect their customers, to avoid an outbreak, and so I think we have an opportunity here to align that regulatory target with the public health target and we'll never have perfect science. Science always asks questions. We won't have perfect data, but we have enough data to know that what we have now is not working, that we can do better in terms of the standard and I think I'm hoping that the conversations we have together over the next few months really focus in on that. So can we get a better system that's going to work for all of us?

Sally Ann: All right. Thank you for your comments, and we'll see if either Andrew or Sean have joined. No Andrew and no Sean either.

Robert Witte: All right, thanks. So here's where we'll open it up to the panelists. Any questions for this group?

Dr. Denise Eble...: I guess seeing as we have a couple of minutes, Claire, were you finished with your comment or was there anything else you wanted to share with us?

Robert Witte: Claire, did you want to say anything? Looks like you're muted right now.

Dr. Denise Eble...: You're still muted unless you're done. Oh, can we unmute Claire?

Claire: Thank you. All I just wanted to say that we've been working, just that we have been working with the private industry organization, building that trust and now we're moving to form with the goal of the preliminary agreement to form two working groups that help us move from the goal of sharing data to actually establishing a legal working group that finds a way to do that where both groups are willing to share data and also a data criteria working group. So that was the last thing I wanted to say, and I also want to just add that we know the immediate goal is this risk assessment. We believe that this will work to form other risk assessments in the future and the platform is really important. Thank you.

Dr. Denise Eble...: Claire, could you comment on what you're seeing or what you're experiencing as the greatest challenges or barriers to accomplishing the work you're describing?

Claire: The greatest challenge and the greatest concern really is that legal mechanism and whether or not there'll be punitive damages associated with that. I think I've heard the industry organizations in the private sector, they understand the benefit, they're willing to share data, but they just want to make sure that it's done in a way that it doesn't come back to haunt them and I think this is a really going to be a critical challenge to overcome that, and they also come to agreement what data and what format it should be in that it can be used because data is collected differently and the boundaries, you want to make sure that it's used in the correct way, and industry organizations have been really positive about recognizing that these things need to be overcome.

Dr. Denise Eble...: Okay, thanks. I mean, we've talked about this before, Claire. As I understand it and the FOIA rules, the kind of data we're talking about being shared would not be releasable under FOIA because it would be sort of business confidential, but that would still have to be go through the FOIA process if such data were FOIA, but I think there is a path forward for this. I don't know if either of you, Claire or Sarah, had any comments or thoughts on the data sharing I was talking about here, which is really, if under this proposal for process control data, we would possibly ask industry to routinely submit that to headquarters. It's already available in plant, but to submit it to headquarters. Any thoughts on that or issues associated with that?

Sarah Sorscher: Well, I'd say that I agree with you, the legal challenges are surmountable, but I think there's a trust that needs to be built. They have to have assurance that it's not going to be used for regulatory purposes and they have to understand that it's going to be kept confidential, but I think probably the more challenging thing is just making sure that the data are useful and used by FSIS because of the diversity in the way companies collect information and that might be aligned with the company's needs, but not necessarily what FSIS needs. So I think that's going to probably be the more difficult challenge, and it might be a long discussion and conversation because I know companies are willing to share. There's plenty of companies who are ready and eager to share, but yeah, that technical piece is going to be the real challenge.

Dr. Denise Eble...: Thank you.

Claire: And I concur with what she just said. I think with the new aspect, the new what you're talking about, additional data, I think putting it in a format that it can be combined and used as a larger database instead of having separate databases would be very useful.

Dr. Denise Eble...: I mean, potentially, this data could be collated by the agency and shared back so that folks could compare themselves to the rest of the population. These are options that we're considering looking at as we talk about, as we consider what should go into our proposal.

Claire: I think that's great. I think it will show industry where they stand. These are the other groups, very positive.

Robert Witte: All right. Any other panel questions here or can we keep moving? All right, let's go ahead and go to the next slide. So again, just that reminder, put your hand up if you're in the group here and we'll get you unmuted.

Sally Ann: All right. We will go to the first commenter. When the pop up appears asking if you'd like to be unmuted, please accept it. Go ahead. You've got two minutes. Remember to introduce yourself before you begin your comments.

Speaker 16: All right, thank you. Can anybody hear me? Hello?

Sally Ann: Yes, we can hear you.

Speaker 16: All right. So thank you for the opportunity and my name is [inaudible 04:21:41] from Tuskegee University College of Internal Medicine. This is not really per se comment, but this is something that we worked in the past 10 years and I would like to share with this committee. Outbreaks by have not been declined in the past 15 years, and even worse, different *Salmonella* serotypes have emerged every year as the agents [inaudible 04:22:04]. With a small funding obtained from USDA, we have developed a general array for the [inaudible 04:22:14] 23 different *Salmonella* serovars. These serovars were selected based on their significance as outbreak causing agents in the past two decades.

Serovars of *Salmonella* included in the genovar [inaudible 04:22:33], and et cetera. So this genovar was validated using over samples including chicken, pork, milk, and fresh produce. Validation results were [inaudible 04:22:54] so the same samples tested by the [inaudible 04:22:59]. These genovar rapidly and the identification of multiple *Salmonella* serovars from a single suspect sample. Because of time intensive nature of manual procedures such as screening for multiple *Salmonella* in one [inaudible 04:23:13] is not included in a standard isolation protocol adopted by different labs and diagnostic centers. Therefore, by allowing the possibility of a screening, these two advances our ability to rapidly and confidently detect multiple *Salmonella* serovars. Currently, this

technology has received [inaudible 04:23:33]. I don't know if I'm on time. I know I was rushing it. Thank you, everyone.

Phillip Bronste...: All right, Thank you for your comments. We'll go to Ashley next because Kelly has withdrawn and Angela is not on the webinar at the moment. So Ashley, your turn.

Ashley: All right. Thank you. We appreciate the agency's interest in data sharing, which has been a point of discussion between NCC and FSIS for years. We welcome-

Ashley: A discussion between NCC and FSIS for years. We welcome FSIS's interest in developing a more secure data sharing pathway and hope that comes to fruition. Data transparency is especially important for critical regulatory and public health decisions. For many months FSIS has talked about the *Salmonella* framework, but in all that time has not provided detailed compelling scientific data to support the appropriateness of the framework. The current process seems to presuppose that a different approach is needed with the suggestion that data will eventually be developed or released.

We believe it is critical that we all start with the robust data and from there collaborate on the best way to approach salmonella control without being provided the underlying information. Presumably driving FSIS's proposed framework, it is impossible to provide me meaningful feedback or know whether the proposed regulatory changes will improve public health.

FSIS has alluded to various analyses and risk assessments and we ask that those be finalized and published before embarking on a fundamental change as to how chicken processing is regulated. Regarding testing, platforms must be readily available, affordable, and accurate with quick time to results. The agency's selective platform has a limit of detection at 10 CFU per gram and estimation techniques would be necessary to determine levels below 10 CFU per gram.

We do not support setting standards based on estimates. The framework raises many questions about industry-wide testing capabilities and will require significant expansion in laboratory capacity to include brick and mortar. It will also result in significant logistical challenges of obtaining supplies, manpower to collect samples, just think about high path AI risk for pre-harvest testing and shipping samples from remote areas just to name few.

We look forward to a continued meaningful dialogue with FSIS on the proposed framework and are hopeful we can come up with a science-based data-driven approach that will not only impact public health, but also ensure that consumers of America's favorite protein still have an affordable product available to feed their families. Thank you.

Tegan: Thank you for your comments. And as both Kelly and Angela have withdrawn from this comment section, I will now turn it back to the moderator.

Robert: Thanks. So again, any panel questions for this group here? Again, I know two folks didn't comment there, but any questions for this group?

Dr. Hale: Yes. Hi. I'd like to make a question or ask a question for Ashley. You mentioned 10 CFU per gram and I think you said something about it being the maximum. Can you elaborate a little bit on that point?

Ashley: Thanks, Dr. Hale. Well, I'm not a microbiologist so we'll start with that, but my understanding is that the selected platform the agency is using has a limit of detection at 10 CFU per gram and that through enrichment then that can get lower, but it can get below 10 CFU per gram, but that's using more of a regression model and, I'm using air quotes, "estimation" at below 10 CFU per gram. And so I think that we're concerned about setting standards on estimates and we'd prefer to use hard data in order to set standards.

Dr. Hale: Thank you.

Rachel Edelstei...: Ashley, could you also clarify as far as submitting data? I mean I know a lot of the poultry establishment submit data using the, as part of the waiver process, the SIP process, I mean that kind of model seems to work, right?

Ashley: Yeah, that's been in place for a very long time and the agency has a ton of data from those establishments so that yes, that's worked so far.

Rachel Edelstei...: But you're looking for some, it sounds like you're looking for something else.

Ashley: Well it seems like the agency has a lot of data needs and the industry has a lot of data and it's trying to figure out how we can get perhaps more granular data than the SIP data to the agency in a way that, and I think Claire mentioned it earlier, that wouldn't have a negative impact on the submitting establishment, so we're trying to just figure out what that pathway would look like. And I've talked with Dr. Eblen at length on how we may be able to move the ball on that.

Rachel Edelstei...: Okay, thanks.

Todd Reed: Yeah, let me jump in real quick. So I'm not a microbiologist either, but I'm pretty confident that the information you received actually on our lab methods is incorrect. And so I would suggest that at some point we'll find a way for FSIS to respond to you directly and get you the correct information so you can understand how the lab methods work. But yeah, it's not estimating and I'm pretty sure there's others on the line that have more detail on that.

Dr. Denise Eble...: Yeah. I could jump in a bit, Todd. So, well, just to get into a few weeds I guess as we look it, right now we work on poultry rinse aids, so carcass rinse aids, which

is basically 400 mls of diluent, buffered peptone water to a bag with the carcass, shake it up, get that diluent off, and that is used to, that's sent to the lab for analysis.

And it goes, as it's prepared, one aliquot, one portion goes off for presence absence for *Salmonella*, and the other is sort of saved for a short period of time until we get the positive negative. And then if it's positive, then we can enumerate what's in that aliquot and so there's no enrichment there to unduly change the number.

Yeah. So we are confident that we can get it down to one CFU per gram. Also, we have done extensive studies when, well before we started doing this, the enumeration before we introduced it to the lab, we did extensive studies to see with spiked studies spiked a very low, very, very low concentrations towards the very limit of the test to see if we could recover salmonella and we could count it.

So we're confident that this is the best technology available on the market at the moment for enumeration. And as with other methods as the very first non-0157 STEC method or 0157 STEC method, all of these were improved over time. This is a good method that works for us right now. We're continuing to look at expanding it out to other commodities and so I would argue that it's certainly not an estimate. We do get numbers that we can rely on. And it's the bioMérieux method. If anybody's interested, it's in our microbiological laboratory guidebook, which you can find just by entering that search term into the FSIS website, and it should be there.

Dr. Hale: Yeah, I would just add to Dr. Eblen's point, when I identified this method as the one that we wanted to adopt was based on results of our in-lab validation study. We used spiked samples and were able to get results that gave us a lot of confidence that the result that we were seeing actually aligns with reality. So I think that's the most important point to take home. So we validated it and we feel confident in the results.

Ashley: Thank you Dr. Hale and Dr. Eblen. It would really be helpful to see the results of that lab validation study that you mentioned, Dr. Hale, and I don't know what lower limit of detection you were using for the bioMérieux platform, but that would be useful information as well.

Todd Reed: All right, thank you. We appreciate that feedback. I think the other point I wanted to talk on the data and it was good to hear, Ashley, that you, in your response to Rachel's question that you're good with how the SIP data is handled because I can confirm that for any data submission, whether it be voluntary data submission or the data submission that we were talking about here today in this crosscutting section where we take the data that's currently shown to implant and put it into an IT system, just like the SIP data that would follow the same process that any data submission would with FSIS where there would always be rights.

Someone can request it, but there's always submitters rights and it goes through that process and the data would be protected exactly the same way. And so I know I think a lot of times we get caught up in conversations, but yeah, if people are good with the SIP process, this is the same process for any data submission.

Robert: All right, Any other questions from the panelists? All right, let's go ahead and keep moving to the next slide. So again, similar to the last ones, go ahead and raise your hand and we'll get you unmuted.

Tegan: Right. We'll start with the first person. Michael Hansen, please go ahead. Don't forget to introduce yourself before you start speaking.

Michael Hansen: Hi, this is Michael Hanson from Consumer Reports. The two points I'd like to make is on data sharing. We absolutely agree with this. We think that FSIS should be getting the *Salmonella* and indicator organism data from [inaudible 04:34:10] and post show and we think it's a great idea that that would be regularly shared with FSIS electronically. The more data they have, the better it is to be able to analyze how process control is working.

In terms of the testing for *Salmonella*, again, we think that's a great idea. We think doing the serotypes is wonderful, but for your KPI, when you said for all poultry you're only focusing on enteritidis, typhimurium, and [inaudible 04:34:42] and that number will be for all poultry, chicken and turkey, we think they should be separated out because for turkey in all of your *Salmonella* sampling from 2016, you've never detected enteritidis, [inaudible 04:34:57], which has caused outbreaks and that is there, so we think reading should be swapped in.

And we also, for the denominator, we don't think it should be the average of all *Salmonella* tests for the previous, what is it, four years. And the reason for that is in part because the sampling numbers are changing. For example, from 26 to 2019, the number of *Salmonella* samples in your verification sampling program increased 40% in chicken from 16,333 to 22,859. It increased 35% in turkey.

So we think that actually just doing it on an annual basis works better. And again, we'll send you this, but we've shown that that actually tracks better with the IFAC data. If you separate out chicken and turkey and if you use just the present years rather than an average for the past four years, because since the number of samples aren't the same as the years go by, then that means you're not getting a true average of the four years.

Tegan: [inaudible 04:36:03] interrupt Michael, but your two minutes-

Michael Hansen: Yeah. That's it. Thanks.

Tegan: ... has ended. We'll go to the next person on the list. Devendra is not on, so that would be Mitzi.

Mitzi Baum: Thank you. I thank you again for the time today to speak. With regard to cross-cutting issues recalls continue to be an issue for consumers and pulling products and I'm interested in hearing what type of recall authority FSIS would have if products are put into commerce that don't meet whatever the new standard may be, a finished product standard.

And then with regard to small and very small businesses, I understand that they're very lean operations. However, I think it's important to state and you can't overstate that bacteria doesn't discriminate whether you're a large farm or you're a small farm or manufacturer of poultry. And in order to put product into commerce, it should be part of your business plan, it should be preventive and that's exactly what we want here as consumers.

The standards are there to protect consumers. Alternative standards aren't acceptable. The framework focuses on prevention and that's what every producer, regardless of size needs to embrace. Continuing to state that the consumer is responsible to handle and cook the product, it is not preventive. The consumer's job is to purchase the product. The manufacturer's job is to put a product into commerce that is safe for those that want to consume it. Thank you.

Tegan: Okay. Thank you for your comments, Mitzi. Let's see. We'll go to Trey next.

Trey: Hi. Small processors have served America in a very different way than large processors. We are not vertically integrated. In most cases we do not own chicks and feed and we are not multifaceted in our ability to further process products. We process for smaller independent growers, organic growers, pasture raised and heritage breed growers, and a variety of other poultry that is not widely commercially available.

As the USDA have data on salmonella's sickness related to small processors, we are not the same type of establishment and we should not be treated the same. Small processors should not be put out of business. The question shouldn't be what would work for you? The answer is easy. Don't place regulation on our sector of the industry without an understanding of the economic effect and cultural effects. Question should be, is this viable for small processors? The answer is no.

Without appropriate technology and guidance on how to eliminate *Salmonella* at the plant, we're left on our own with no resources or funding to reach regulatory compliance. We already have to navigate an inspection service that has a difficult time appropriately regulating small plants, the never-ending pursuit to understand regulation and meet compliance occupies a small processor's life.

Now, the heavy burden of *Salmonella* as an adulterant is an extreme risk to us staying in business. While that may sound extreme, consider that there are very few small poultry processors in America. They're not publicly owned and business loss is not passed to shareholders. It is passed to the families that work at the plant, the farmers' children who are growing up in a world where the small farm is becoming a story of the past, and the butchers and small grocers and restaurateurs who uphold small businesses in America.

Small processors deserve the opportunity to stay in business in the face of impossibly difficult regulations. It cannot be that the USDA believes it can enact regulations so different from current regulations and expect the independent small-processors to figure out compliance without appropriate support. Thank you.

Tegan: Okay. Thank you for your comments, Trey. And now I'll turn things back over to the moderator.

Robert: Thanks. So again, for this group of four or this section here, this slide, any panel questions? Any questions for the group here?

Philip Bronstei...: I'd just like to respond to Mitzi. She asked a question, a specific question about recall authority. And just for folks on the phone, in case you're not aware, FSIS recommends recalls and the industry carries them out. In the absence of a recall, if FSIS does believe that there's adulterated product on the market, which would be injurious to a public health, we can seize and detain product outside of a recall.

In both cases we would, a recall is accompanied by a public notification and a seasoned detention would also be, it would have a public notification associated with it also. In the time that I've been with FSIS and this, I don't even know that we've ever done, had to go as far as doing a seasoned detention because an establishment just wasn't interested in doing a recall product that we could demonstrate was injurious to human health.

So I would say that's a testament to our science-based data-driven regulations and our way of going through carefully setting up our regulations so that they can be enforceable in the marketplace and defensible in the marketplace, even in the eyes of a product recall that's out there, so I just wanted to make that comment. Thank you.

Rachel Edelstei...: And I wanted to follow up also on that issue. If we did set up product standards where *Salmonella* level, *Salmonella* would adulterate certain product and if we're testing for that product, the establishment would not be able to move the product into commerce until acceptable results were in place. So that would also be addressed. Then there would be no need for a recall if we set up standards like that.

Todd Reed: All right, Robert, I have a couple things. First I just wanted for Michael, just to clarify that the KPI that you're discussing is not part of this framework. It is a independent measure that FSIS has to kind of measure the effectiveness of our policy. Excuse the same word twice, but point being is its independent from this framework where the stereotypes that we look at in this framework don't have to match what's in the KPI. And so we really would look for your comments, your written comments on that, that you were describing on how we would take that into account in the framework. And I didn't know if you wanted to say anything else about this.

Michael Hansen: Yeah, I mean I think since you do take that data in your seminal of verification, you do take data on what all the serotypes are. So you could be continually looking at which ones are coming to the top. The only reason that we hammered on those is again, when we looked at the data, we found that those three, that it didn't vary drastically from year to year, but it was consistently those three, for example, in chicken getting responsible for a higher and higher percentage.

So yes, should you be looking at all the data and all those? Absolutely. And whichever are the top, say three or four, if they're being responsible for more than 40 or 50%, then yes, focus on those. The only reason that we focus just on those three is because they track illness and they were consistently, at least in chicken, going up in time from the data that's already there.

So we just thought that since that's useful, focus on those in the immediate future, but as you go forward, yes, you're already collecting data on all the *Salmonella* you do. You serotype it. So you can already see which ones are coming up to the top and the top five or 10 and what percentage of all serotypes those are. And then when the IFSAC data comes out, you can see how it compares to that.

And I know it's going to change when the new whole genome sequencing random sampling model comes up, it'll make *Salmonella* even more important for chicken. So anything that you can do that will track with illness, use whatever serotypes you can. And I think the data will show that. We're only saying from our narrow look at the data that's already there. You are great on the right mark for picking those three.

Because again, I'll just recall in our ground meat sample, those three you chose were 92% of all the *Salmonella* serotypes we found in ground chicken, so that means you chose correctly. If the data become different in two or three years, fine, move to those. But it seems to be consistent and it's going from year to year.

That's why if we had looked at the data and for example, that KPI had varied drastically from year to year, then that would suggest that it's not useful. But it does appear to be very useful. So use it until it's not useful anymore. But yes,

look at all the serotypes. You already have that data, it's just you need to more effectively look at it and I hope this helped.

Todd Reed: Yeah. All right. Thank you.

Robert: Okay.

Todd Reed: I guess I had a question for Trey, Robert, and then maybe we're ready probably to go to the next group after that. So Trey, we've heard you loud and clear on we need to take establishment size into account and I know we had some other commenters earlier today and maybe we'll find a way in a little bit to see if we can hear from everyone, but while you're on this group, I just wanted to ask, do you have any suggestions on what would make sense? What is it that small plants could do, or what is it that we could be looking at? I think we'd be open to hearing from your perspective, what does make sense.

Trey: Yeah, there's a lot that we could do, but we don't know the technologies out there. We don't know what the larger plants are using, and we're just afraid that they'll be able to adapt quicker than us and they'll be able to absorb the changes quicker than us.

And so technical data, technical information, all the things that are enacted by these larger plants are not going to be widely available to plants like us. So we just feel like it's going to be very difficult for us to try and figure this out when it's already been difficult for us to figure out *Salmonella* and we just don't have a sense of how we're going to do that and stay around.

And I'm not really sure how to answer that other than we want to know how to do it, we want to know how to be compliant. Of course, we want to do this, but there is a bigger picture there that we're most at risk and it's not just us who's affected. You just take the plant out. Well, there's a whole bunch of small growers and other businesses that rely on us and they rely on us to know how to do this. And just knowing how to do this with a snap of a finger, isn't what's possible for us.

Robert: Okay. Thanks, Trey. And we'll, let's go ahead and move to the next slide and then we may end up circling back to that as the bigger group. So again, raise your hand to get in the group here and we'll start at the top there with Melissa.

Tegan: All right. Melissa, there are two of you currently logged in on Zoom. Could you please raise your hand on the one you are currently looking at so I can unmute you? All right. I have been told that Melissa has no comment, so we'll go ahead and go to Santhosh. All right. Go ahead and click on the button to unmute yourself if you'd like to make a comment at this moment. All right. We'll go to Thomas, commenter 15 next.

Thomas Gremilli...: Okay. I like others, I misunderstood the prompt here, but that's not going to stop me from talking. So I wanted to just say thank you for putting on this process first of all, and these are great questions to be asking.

On testing, I think it's very important that FSIS recognized that its standards are going to drive innovation in the testing industry to at least some extent. We didn't have a cheap rapid test for a Coronavirus until circumstances demanded it. Maybe that's overselling this, but I got to think, and I'd like to hear your take on this.

If there is a standard for, final product standard that turns on the presence or a certain level of salmonella enteritidis or typhimurium, what have you, I got to think there's got to be a rapid onsite testing option, an affordable one available to detect that. And I'd be curious as, if you think that's just overly optimistic.

On testing, I think it's great that you're thinking about this and there definitely should be a process for establishments to share sampling data. I will emphasize that there are a lot of carrots that the agency can use here, just like with the *Listeria* program, there are ways all of your regulations can be varied essentially to create incentive for establishments and companies to share their data and you should take advantage of that.

And I agree with what Sarah said about the challenges of making that useful to you, but I think those are surmountable. And finally, with respect to the small producers, I would be curious, and I wish I could provide more information about this, but I'd be curious what Europe has done on that front and how other jurisdictions are wrestling with that, because I agree it does seem like a difficult issue. Yeah. Thank you.

Tegan: Thank you, Thomas. And Chelsea has withdrawn her comment from this section and Santhosh unmuted himself, so I'll turn things back over to you, moderator.

Robert: Hey, perfect. Just wanted to check. We had Andrew at the very beginning. I just want to check, can you see if he's in at all? Maybe we can get his hand raised. Otherwise, we can open it up to more folks.

Tegan: No, I'm not showing Andrew Lawrence. He is not on the webinar at the moment.

Robert: Okay. So with that, I guess panelists, any questions for this group here?

Rachel Edelstei...: This is not really a question. I just wanted to note that in our framework we made it clear that we are concerned with the small businesses. One thing we've talked about was FSIS could potentially collect and test the samples at rehang and post-chill that would save on costs. And we talked about providing more time to the small businesses to meet regulatory requirements. And we would

certainly request comment on that, on those ideas and others that would work with small and very small establishments.

Robert: And so maybe we can open it up to the whole crosscutting issues group here, everybody on here. Again, the topics are testing for *Salmonella*, data sharing and alternatives for small and very small establishments. I think we touched a little bit on the small, very small, but does anybody else have any ideas for what they were thinking for small, very small or what could work? Or, I think Trey touched on a little bit, but any questions or suggestions there?

Todd Reed: And Robert, I think there were some others representing small and very small and other sections of today's meeting as well. And if those people wanted to raise their hand and possibly queue up just to get more input on this specific issue, I think would be helpful.

Robert: So I see Thomas' hand up. Is that still legacy?

Tegan: That's still legacy.

Robert: Perfect. All right. So again, raise your hand. Any input on small, very small? Anything else in this section?

Philip Bronstei...: So if no one wants to raise their hand, I'll talk a little bit about our process in general for small and very small establishments. I mean it is something that we obviously focus on a lot. I think about 85 to 90% of our establishments that we do regulate are small and are considered small and very small by FSIS.

So it is always a challenge for us to try to make that policy applicable to as many folks as possible because I think it was Mitzi who said that bacterias aren't discriminatory. They're present in all of them and there's a potential for adulteration at every establishment out there.

But our process by and large is to establish policies that we think will work for large, small and very small and then gather data from outside the agency, inside the agency and from the larger industry to try to make guidance documents and we have a lot of guidance documents on our website, and those are specifically for small and very small establishments because we do realize it is a big challenge out there.

I do think, kind of to draw things together, I think that's one of the main benefits that we heard from our friend. And I'm sorry I forgot your name, was it Claire from University of Maryland talking about data sharing. And I think data sharing is one of those things that we really can, if we can get the best practices from large establishments and let small and very small establishments know there's a lot of choices out here, but here's what our data is showing or here's what the data we have access to is showing is the most effective and efficient way for you to address these hazards. And then data sharing will go a long way to help that.

So I think we can draw in data sharing as being a really a key component amongst the industry so that we can really ensure that small and very small establishments can not only persist in the marketplace, but also provide just as safe as a product as a large and very large establishment does out there. So I think that it's great to have these comments together because I think as we call this a crosscutting issue, it really is. I mean, everything that we're talking about here, we want to be applicable to as many folks as possible-

Philip Bronstei...: We want it to be applicable to as many folks as possible. Hence, our flexibility that I think HACCP allows for us and realizing that there's some retractors from HACCP talking about how it's never been fully implemented. And that's what we're trying to do here, I think in this comment period, is understanding where the weaknesses that we see that HACCP may have or our current regulatory processes have and improve upon them, because we have seen percent positive for *Salmonella* go down on chicken products, but we haven't seen a commensurate shift in the number of salmonellosis associated with chicken products. So, we really are looking for new ways to put all these pieces together and make a difference out there.

Hany Sidrak: I'd like to add a little bit more to what Dr. Bronstein just shared with us. And there's definitely a great support for very small establishments through FSIS. We do outreach efforts and there's also support from extension service. I also want to just say that I understand the challenges that was mentioned earlier as far as the vertical integration in this poultry industry and as far as slaughter. I also want to say that I see from my perspective, from the very small or poultry slaughter operations than I have seen. Less mechanization, so less equipment, more manual processing of the birds. And I'm just wondering if that actually is an advantage, kind of like a possibility of maybe minimizing cross-contamination. Of course you're dealing with a little bit different environment as far as being able to rinse and minimize cross-contamination as people control that process as opposed to a higher line speed with a lot more mechanization. So I'd like maybe some comments or maybe some specific data that's specific to very small establishments that could be shared with us. So we could also consider it in our process here. Thank you.

Mr. Robert Witt...: Again, if you got any comments, please raise your hand. Looks like Todd came off mute.

Todd Reed: Yeah, I didn't see any hands on the small and very small and so I guess if anyone has things on that, please submit them written wise, I think that would be helpful. But I wanted to swing back to the *Salmonella* and just see if anyone else on this cross-cutting group had thoughts on the FSIS framework statement of, we're really wanting to evolve that across time as science evolves and just say out upfront, we want to get to where we can use the best possible data. So maybe we start with enumeration and then when the science catches up to the speed that makes sense, we can go to serotype and then consider even possibly going to specific genes after that and honing in more and more on specific *Salmonella* that causes illness as opposed to all *Salmonella*. Comments posed on

that process at a theoretical level, but also I guess as a practical level. I see a few hands Robert.

Mr. Robert Witt...: I'm not seeing them here. Event producer, do we have any hands up?

Todd Reed: I think Michael and then Ashley.

Michael Hansen: Yes, this is in response to what Todd just said. I think that's actually a great idea to have this enumeration data. It's very important to have that and I think it could be used very effectively as well. I'm sorry, I lost my train of thought there.

Todd Reed: No, that's all right.

Speaker 17: It's a long day?

Michael Hansen: Yeah.

Todd Reed: Why don't we turn to Ashley, Robert and then Michael if you want to jump back in.

Michael Hansen: Yeah.

Ashley: Thanks Todd. A good question. I think it's important that regulatory policy be built on current testing capabilities and not a capability that could come in the future. And like you mentioned, if testing capabilities do change over time, which they do and they will, then we get back together and have a conversation on how we could change the regulatory framework as opposed to setting a regulatory framework based off of something we hope we get to in a couple of years.

Michael Hansen: Yeah, I know what I wanted to say now. And that is what I agree with Todd about is, when they move to more things, testing for specific genes or virulence factors. It should be pointed out, for example, for salmonella infantis, most of the illnesses seem to be associated with this inc, this large inc plasmid, which is moving around between various strains of *Salmonella* infantis. And that plasmid has multiple genes for antibiotic resistance and adhesion factors and virulence factors. So what you might be in the future doing is not just looking for a specific *Salmonella*, but saying that the problem is this particular mobile genetic element, this inc plasmid for example, that has a pathogenicity island, multi-drug resistance, adhesion characteristics, all those other things. So maybe in the future besides looking for the *Salmonella* bugs, you might be looking for these mobile genetic elements, these large mega-plasmids that have both virulence and all of these things on them and that those should be looked for.

And if they're detected at all on a piece of meat, you remove that because since they are mobile, even if you don't see them at the moment in a pathogen, they can move in. So I do think since we now know that many of both genes for

resistance and pathogenicity and virulence and other things are often on these mobile genetic elements. And so as the ability increases in the future, you might want to focus on, for example, making that an adulterant, these mega-plasmids themselves so their levels can be decreased or gotten out of the food supply. Thank you.

Mr. Robert Witt...: Thanks Michael. I see Thomas up.

Thomas Gremilli...: Yeah, I want to chime in and just say the testing exists. It's not particularly cheap, but going off what Michael said, I do think eventually the holy grail is virulence factors, right. And being able to discriminate between the kind of non-virulent, virulent *Salmonella*. And you can push the evolution of the testing technology while giving establishments some breathing room by virtue of enumeration standards. If the testing for the particular stereotypes is a little clunky to begin with, then maybe they'll be more of a focus on just bringing overall *Salmonella* levels down.

But if you've got a standard there, I think it's going to create incentives so people are going to want to make money selling those tests and to just assume that the testing technology is just going to stay the way it is and that there's not an endogeneity problem here with FSIS being the major player in this field and really shaping where resources are invested, I think that would be a mistake. So yeah, I think you don't have to just have faith that something's going to come out of left field that doesn't exist. But there should be some recognition that the policy's going to drive the testing and test against the standards are going to come down in cost. Thanks.

Mr. Robert Witt...: Thanks Thomas. All right, so that completes this session or this part here. Let's take a 10 minute break. I have 3:31, so depending on your time zone or 3:30 depending on your time zone. We'll start again at 31 after, so 3:31, 4:31, but 10 minutes from now.

Shayla Mae Bail...: All right, welcome back everyone. We're now going to transition to our open comment period. I am Shayla Bailey and I will be the moderator for this portion of the event. For those on Zoom, please feel free to place yourself in the question queue by using the raise hand feature if you wish to make a comment or a question. And that's located in the toolbar at the bottom of your screen. For those of you on the phone, you'll need to press pound two to enter the question queue and you may also enter your questions or comments into the chat. And I want to remind you that all of the comments and questions submitted via chat are being captured as part of our public record today. If you're called on to speak, we ask again that you limit your comments to two minutes. If you are still speaking after two minutes, then our event producer will let you know that you've gone over time and we'll need to move on to the next person. So I do see Pat Buck's hand up, we can go ahead and take Pat.

Pat Buck: Hello, this is Pat Buck and I want to thank FSIS very much for its wonderful interactive public meeting, which was done virtually. I thought it was very

interesting and I thought you had a wide range of responses, which was very encouraging. The one comment I have is that CFI agrees with Philip Bronstein that the data sharing is a cross-cutting issue that needs to be resolved. Barbara Kowalcyk is a leader in this area and would welcome future discussions about ways to improve FSIS's data programs as well as ways to allow industry data to be shared. Again, I finally encourage FSIS to review today's comments and plan technical meetings that can further investigate important topics and identify potential gaps. Again, thank you very much for this wonderful meeting.

Shayla Mae Bail...: All right, thank you, Pat. Again, if you wish to make a comment or ask a question, please go ahead and raise your hand. For those on the phone, you can press pound two to enter the question queue. All right, Katie Rose, I see your hand up, please go ahead.

Katie Rose: Great, thank you. Just listening to a lot of the things we did today. Just an off the cuff comment I would like to make is underscoring something that a previous commenter said is, to really have a risk based program that's going to really help consumers really get to understand the attribution information more. What really is making consumers super sick as it does? Breaded stuffed, not ready to eat, but looks ready to eat products? Is it chicken livers? Is it ground chicken? Is it chicken parts? Do we really have a better understanding of the true attribution of what's making consumers sick? Of being able to target those? I think we're going to be chasing our tails a little bit. So I really want to underscore, I think it was Dr. Peterson who brought up more of a survey or baseline of the entire poultry industry to better understand risk, that we can move forward in a science based, data driven way. Thank you guys so much for this comment period. We really look forward to working with you more.

Shayla Mae Bail...: Thank you. Martin, I see your hand up. Please go ahead.

Martin: Thank you. So I heard a lot of talk today about the importance of these new policies being risk based. But I'm a little bit concerned and maybe also a little bit surprised how much of the language and even examples that were used were still very hazard based and not risk based. We talked about things like, "We don't want any *Salmonella* levels that cause human disease." That's not risk based because we are not going to achieve that. Every *Salmonella*, even a single salmonella has a finite ability to cause human disease. So my challenging question is, we have healthy people 2030 that sets a target for *Salmonella* levels with regard to human disease that we want in the year 2030. I've no heard, no mention of that today, and I would want to challenge the agency to see how they can link their targets to our targets in healthy people 2030 with regard to *Salmonella* numbers in that year. Thank you.

Shayla Mae Bail...: Thank you for that. All right. I am not seeing any additional hands raised. I do have a comment that came in from Michael Hanson, saying many thanks to FSIS for holding this open meeting. It has been very useful and informative and I had so much to say in each comment that I didn't have time to thank FSIS for holding

this listening session. Well, thank you Michael. All right, Brooke, I see your hand's up next.

Brooke Schwartz: Can you hear me now?

Shayla Mae Bail...: We can, yes.

Brooke Schwartz: Okay. My name is Brooke Schwartz and I'm with Rheonix. There's been a lot of discussion in this very helpful meeting about whether the testing technology is available to address stereotyping with acceptable timely results. I just wanted to mention that Rheonix has a highly multiplexing PCR based technology that we're currently using from the stereotyping directly from an enrichment. We'd be interested in deploying this technology for salmonella stereotyping. For us, the greatest hurdle to designing the assay is getting clarity on what stereotypes or other subtypes we would need to identify and what sample types we need to focus on. So as we move forward in this process, we would be very interested in talking more with USDA, as well as some of the other potential partners from this call to develop an assay that meets the needs of industry as well as USDA.

Shayla Mae Bail...: All right, thank you for that, Brooke. Ashley, I also see your hand up. Please go ahead.

Ashley: Thank you Shayla. I just wanted to wrap up today by thanking the agency for hosting this public meeting and for listening to and taking into account industry feedback on the *Salmonella* framework. Food safety is a top priority for all of us, as is protecting public health. We support changes in food safety regulations that are based on sound science, robust data, and are demonstrated to positively impact public health. We do believe that we need to reevaluate the current regulatory structure and use a risk based approach to make decisions on what changes may positively impact public health. We encourage the agency to finalize and publish the two risk assessments, and we hope that that information will help guide any regulatory changes down the road. Thank you again, and we look forward to continued productive dialogue with the agency.

Shayla Mae Bail...: All right, thank you, Ashley. Again, for folks on the phone, you can press pound two to raise your hand or you can raise your hand in the Zoom platform. Thomas, I see your hand up. Please go ahead.

Thomas Gremilli...: Thank you. I've already talked a lot, but I also wanted to thank the agency for holding this meeting. For taking the initiative on this very important issue. And just to reiterate what others have said, that the current regulatory system for protecting consumers from *Salmonella* in poultry is not working. And so I understand we are all in favor of empirically driven policy, but we should also be mindful that there's going to be uncertainty and you're never going to have all the data and all the analysis that you would like. And I think there, FSIS is on the right track and it's just a matter now of following through and I appreciate all of your hard work. Thank you.

Shayla Mae Bail...: All right, thank you. So I'll also open it up to our FSIS panelists to see if they have any comments or feedback that they'd like to give at this time.

Philip Bronstei...: I think I would like to echo the thanks to the agency back to the folks that are participating in the meeting today. So especially for the ones that have signed up to make public comment on multiple areas of this framework. I hope everyone that does realize that FSIS has really tried to bend open. We've had a series of public meetings and both with focus on science and then comment from the consumer groups and from industry and additional meetings in smaller groups throughout this process. We really do think that food safety is a common goal of everybody who's on this meeting right here. And so we appreciate everybody engaging in this process.

I realize we're not all going to think the same way. We're not all going to say the same things and we won't agree a hundred percent of the time, but this is the way this open dialogue with all groups that are going to be impacted by any future regulations is really, I think a wonderful way forward. And so I want to thank everybody on the open that's done an open comment period out here. And then also if you have additional comments, I'm sure we'll talk about later how to submit those in written formats. So I just want to thank everybody in that attended today, whether you spoke or not, even hearing this as part of that process, which I think is important. But thank you.

Todd Reed: And Shayla, I just wanted to jump in before you turn to Paul for the closing remarks and just tell everyone thank you for the comments. They really are appreciated and we really do take them into account and try to consider. And thanks to everyone on the FSIS side for putting this on. Both the comments, the people who answered questions and the people who ran the sessions that all of you saw as well as many people behind the scenes that put in many, many hours to make this work. We had over 600 people registered and you saw the number of people we had lined up to make comments and today was, honestly flawless. It went really great. And so just thank you to everyone who was involved in that. And I just want to say to reiterate that what Phil said and what Sandra said at the very beginning is, we are trying very hard to be transparent and public.

This isn't rule making, this isn't even proposed. This is a framework before we even get to proposed and we're getting public comment and written comment and then there'll be all the regular comment on that. And so we really are trying our best to engage all stakeholders to get as much comment to come up with the best policy that we can in the long run. And we know that not everyone will love where the result is, whatever that is, we don't even know yet. But we do know that where we end up will be better because we've heard you and taken into account what you have, so that we can do the best we can when going that direction. Thank you.

Shayla Mae Bail...: Thank you, Todd. Absolutely. There's been some great discussion today. I am not seeing any additional hands up or comments coming in. Oh, I apologize. I

just saw one come in from Katie Rose. So she says one other important aspect that seems to be missed. New regulations like naming *Salmonella* as an adulterant could quickly become a food security issue. So any changes need to take that into consideration as well. All right, thank you Katie Rose. So again, thank you for the great discussion and seeing no other new comments or hands raised. I'm going to turn it over to administrator Paul Kiecker for some closing remarks. Paul?

Paul Kiecker: All right, thank you everyone for joining us today and sharing your feedback on the salmonella framework. And I can tell you that this has really been a full day of FSIS listening to all of the comments you were making, asking questions back, taking notes, and we have a large list of ideas and concerns that have been shared here today. So thank you very much and I can speak for the entire agency when I say that we really do value hearing your comments and your suggestions and hopefully you could tell that from our interaction here today. We heard from many of you with a deep knowledge and passion for this subject, and it's through the feedback that we get from you that is going to allow us to take and find an actionable approach to this *Salmonella* concern. From the start, we've emphasized the importance of collaboration in developing the strategy, and that continues to be a priority and that will continue to be a priority as we move forward.

Our job over the next coming weeks and months is going to be to take a look at all the feedback and all the suggestions and comments that we received and incorporate those into the plan as we develop it. And we'll continue to engage with you, find the best path forward that allows us to reach our goals. And that is to protect the US consumer and to ensure that industry has the tools that are necessary for them to succeed. And let's remember why this framework is needed. The agency, the Interagency Food Safety Analytics Collaboration estimates that 23% of foodborne salmonella illnesses are attributed to poultry consumption, 17% from chicken and 6% from Turkey.

And we also need to realize that the regulator products under FSIS are certainly not the only cause of salmonella illnesses in the US. But we have a responsibility to continually seek ways to reduce its burden on the American consumer. And we have struggled to do that in the past few decades, as is indicated by not meeting the healthy people goals that were set for *Salmonella*. So today's remark, today marks an important step forward to reducing salmonella illnesses, which is in line with our vision that everyone's food is safe. And again, I really do appreciate everyone, all the stakeholders, FSIS personnel that are working together here to see that the vision becomes a reality. And thank you for your participation here today and for everything that you do regarding food safety. Thank you.

Speaker 18: That concludes our conference. Thank you for using event services. You may now disconnect.