Public Meeting Process Control Monitoring and the *Salmonella* Framework for Raw Poultry Products-12052024 Meeting Recording

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2h 19m 30s

Bailey, Shayla - FSIS started transcription

Bailey, Shayla - FSIS 1:05

Hello, everyone, we are going to get started in just a couple of minutes.
We still have some folks who are connecting, so I want to give them a chance to do that. So just hang tight with us and we will get started in a minute. Thank you.
Okay, it looks like everyone has connected.
We may still have some folks who are still joining, but we're going to go ahead and get started.
So good afternoon, everyone and welcome to USDA's public meeting where we will focus on process control monitoring and other aspects of the *Salmonella* framework for raw poultry products.
My name is Shayla Bailey and I will be the moderator for today's event.
I'm joined by several esteemed USDA colleagues and a panel of industry, consumer and public health experts who will offer perspectives on process control monitoring as it relates to the *Salmonella* Framework for raw poultry products. Before we get started with our formal agenda, I want to go over a few housekeeping items.
This event is being recorded and transcribed to be included as part of the formal record of comment on USDA's proposed *Salmonella* Framework. Earlier this week, we hosted a public meeting to discuss other components of the *Salmonella* Framework. A recording of that meeting which focused on product standards will be added to the event page on our website in one to two weeks.
A transcript for that session will also be posted.
We have several presentations planned for today's meeting, after which we will open the floor for questions and discussion. We will not be taking questions or addressing the chat during the presentations and remarks. Once we have heard from all of our speakers and have reached the discussion portion
of the call you will be able to raise your hand or use the chat to make comments, ask

questions, or add to the discussion.
We expect remarks and comments to be respectful and productive, focusing on constructive discourse and an exchange of information, perspectives and ideas.
I will provide more instructions on how we will participate in the discussion once we reach the end of our presentations. And now I'd like to introduce Sandra Eskin, Deputy Under Secretary for Food Safety, who will get us started with some opening remarks.

Eskin, Sandra - OSEC, DC 4:23
Thank you, Shayla and thank you everybody who is online right now.
As you all no doubt know, notice and comment rule making is foundational to the government's role in making policy across the whole range of issues.
It's important and the reason we do it is to consider stakeholder comments ideas, complaints, suggestions and whatever else. It's both written, and this afternoon it's going to be verbal. Whether it's rulemaking or other policies, the more input we get from stakeholders, the better the policy. And I just want to reiterate something that Shayla just said, constructive dialogue is what we're looking for.
We understand that this is a proposal and people have many opinions about it.
It would be helpful, yes you can tell us you don't like it or what you don't like, but if you put it in your comments, certainly in your written comments, tell us what specifically might be the issues that are of concern to you, and particularly helpful what alternative approaches do you believe would be better
at getting us closer to our goal of reducing illnesses linked to *Salmonella* contamination in raw poultry and thereby improving public health.
Again, thank you so much.
I'm eager to listen to the conversation. This kind of interactive dialogue is particularly helpful.
Back to you, Shayla.

Bailey, Shayla - FSIS 6:09
All right.
Thank you, Sandra.
So up next we'll have an overview of the proposed final product standards.

Please welcome doctor Michelle Catlin, Chief Scientist, who will go over the USDA proposal with us.

CF

Catlin, Michelle - FSIS 6:21

Thank you very much, Shayla. As I think everyone on here knows, on August 7th of this year, FSIS published the proposed framework to reduce *Salmonella* associated with poultry products, and we published that in the Federal Register Notice.

That proposal is informed by data, scientific evaluation and a lot of feedback that we received from broad stakeholder engagement.

The proposal is available for comment, and all comments must be received by January 17th of 2025, so next month.

I did put a QRS code up on this slide that will get you to that proposal.

Next slide please.

The proposal that we published has three different components.

The second component is what we're going to focus on today and that's the process control aspects of the proposal.

On Tuesday, we did focus on component three, which is the final product standards, but today we will be focusing on process control. Next slide please.

So in the proposal, FSIS did propose amending specific regulations, and that's 9 CFR 381.65 (g) and (h).We proposed to do that to establish new requirements related to how establishments monitor and document whether their processes for preventing microbiological contamination are in control.

In this proposal, we would require establishments to incorporate statistical process control, or SPC, those SPC monitoring principles into their microbial monitoring programs, or MMPs.

In doing so, we would require establishments to use only validated and fit for purpose, microbiological sampling and analysis procedures.

We'd require them to generate and record statistically meaningful microbial monitoring data.

We'd also required them to set benchmarks against which to evaluate their data.

And we want them to otherwise, require them to otherwise, define the statistical methods that they will use to evaluate the data against those predefined limits. Next slide please.

Now we know that some people already use this and have these processes controls

in place; and other ones might not have as rigid or rigorous a system in place.
So we would like to, and we also know there might be challenges for small and very small establishments with respect to testing. So under this new proposal, FSIS would provide eligible small and very low volume establishments the lab services to be able to do the analysis.
We would provide this at no charge, so that we could be doing the microbial monitoring for them.
Also to ensure compliance with the required corrective action provisions, we would require establishments at a minimum, to implement written corrective actions, including a root cause assessment, when their results do deviate from the predefined criteria that the establishments have in place.
Next slide.
Along with all the requirements, FSIS would provide new guidance, including an SPC sampling plan for both at rehang and post-chill locations. As well as well as a one-sided process control statistical model that charts and calculates the process control against the minimum monitoring criteria at the minimum required frequency.
I do want to point out that this is considered sort of a safe haven for people who don't already have their own process controls in place.
As long as the process controls that are in place meet our requirements and are adequate, then they wouldn't necessarily have to use the same link.
FSIS is also proposing to make an electronic spreadsheet that's all pre-programmed to calculate the monitoring measures from the sampling plan, so that that would be helpful to, you know, have this. So, it's helpful to establishments out there.
Next slide.
In addition, we are proposing amending record keeping requirements such that establishments would be required to submit microbial monitoring sampling results to FSIS electronically. To facilitate this, we are developing a web portal for external partners to securely upload and submit the sampling information to FSIS.
This would mean it would be submitted electronically and in a machine-readable format. We would also provide a template to record; for establishments to record and submit their monthly results, either by uploading into the portal or manually entering the information into the portal.
If an establishment was not using the template, they would need to manually enter their microbial sampling data into the portal to submit the monthly data.
Next slide.

So that is just a very brief overview of many of the highlights of the process control aspects of the Federal Register Notice and with that I will turn it back over to Shayla so that we can hear from all of you and hear the discussion which I am very much looking forward to. Thanks.

Bailey, Shayla - FSIS 12:23

Thank you, Doctor Catlin.

We will now transition to our stakeholder presentations. Each presenter will have 13 to 14 minutes to share their thoughts and perspectives with us about the proposed, about the proposed aspects and factors into the *Salmonella* framework.

So first we're going to hear from Sarah Sorscher from the Center for Science in the Public Interest.

SS

Sarah Sorscher 12:49

Thank you, Shayla, and good afternoon, everyone.

I'm pleased to be here with you today.

My name is Sarah Sorscher.

I'm director of regulatory affairs at Center for Science and the Public Interest. Next slide.

My organization, CSPI, is your food and health watchdog.

It's our mission to advocate for policies on nutrition, food safety and health, holding agencies and corporations to account, and empowering consumers with independent, unbiased information to live healthier lives.

Some of our guiding principles include independence, scientific rigor and transparency, and in support of this we do not take funding from the food industry so that we can represent an independent voice for consumers in the food system.

We've had many key victories over the years, including being a leader in pushing for the Food Safety Modernization Act. Next slide.

As we, as we talk today about this proposed framework, we all recognize that public safeguards don't exist for their own sake.

They're there to solve a problem, and in this case the problem that this framework's trying to solve is that hundreds and thousands of consumers are being sickened every year from eating contaminated poultry.

The CDC estimates that more than a million people are sickened annually in the US

from eating all foods contaminated by *Salmonella*, and this bacteria is a leading cause of hospitalization and death.
And of course, the food most likely to cause illness from *Salmonella* is chicken. *Salmonella* in chicken is estimated to cause close to 200,000 illnesses per year and contribute 7 billion in cost to the US economy. Next slide.
So USDA's current standards for *Salmonella* and poultry have not been effective in controlling *Salmonella*, *Salmonella* illnesses. These standards were initially conceived in 1996 and have never gone into full effect due to a court case in 2001 that blocked enforcement of the standards. Since 2006, USDA has used sort of a naming and shaming approach, publishing the names of establishments who fail the standards. Unfortunately, this has not had an impact on human illness rates, and we see here in this data from CDC's Food Net that in the 10 years after the Establishment Publication Policy went into effect, roughly 2006 to 2016, cases of illness have remained largely flat.
I'll acknowledge that there was this dip in 2020 due to COVID, so we may not know the full impact of any recent policy changes such as the decision to expand standards to parts in 2016.
We had a speaker yesterday who said that the prevalence based performance standard did a good job and I would say that the human illness numbers speak to the contrary on that, that the standards the standards have not been effective. And I'll point out that this is in stark contrast to the impact when USDA rolled out product standards for *E. coli* in ground beef in the 1990s. In the decade that followed, USDA's determination that *E. coli*O157:H7 was an adulterant in ground beef incidents of foodborne illness from *E. coli* dropped significantly, more than 40%. So we do know what an effective food safety standard looks like, and the current unenforceable performance standards are not such an effective standard.
Next slide.
And stakeholders all tend to agree on the need for reform.
So too, early requests in this recent push for reform emerged from the consumer advocacy community.
One was a petition by Bill Marler, an attorney representing victims of foodborne illness, and a second was a petition by my organization, CSPI.
Both petitions had broad support from consumer and food safety groups, and both called on USDA to create enforceable product standards for poultry.
And in 2021, we joined other consumer groups, poultry industry experts, food safety

researchers and current and former state and federal regulators to form the Coalition for Poultry Safety Reform, in which we agreed, among other things, that the current system for regulating poultry safety is broken. And that to achieve better results, the current performance standards needed to be replaced with standards that were objective, risk based, achievable, enforceable and flexible enough to adapt to emerging evidence and the latest science.

Next slide.

And the proposed rule that we're here today to discuss is USDA's response to those calls for reform and to its credit, the agency worked comprehensively to address *Salmonella* risk from farm to fork. Looking at pre-harvest, at processing, that is the topic of today's meeting, and end product standards in three components. Now, we heard comments on Tuesday that we don't have enough data to support reform efforts, but the work that went into this framework speaks to the contrary.

This proposal is supported by two peer reviewed risk assessments.

A peer reviewed risk profile both informed by extensive FSIS sampling data and literature review and in support of component two of the framework. USDA has produced an evidence based model for statistical process control, and the agency also sought feedback in multistakeholder meetings, including the one that we are at today, consulted with the National Advisory Committee on Microbiological Criteria in Food (NACMCF) method and they allowed more than 160 days to comment on the role, which is an unusually long comment period. Conducting science-based policy means that that you can move forward with policy improvements while also seeking to fill evidence gaps, and the Coalition for Poultry Safety Reform affirms this in one of our other foundational principles. When we said the science has advanced sufficiently to support regulatory improvements today, while also noting that ongoing research is still needed.

Next slide.

While the framework is well supported by evidence, there are areas that the policy could be improved, and this includes addressing food safety pre-harvest.

Initially, USDA had indicated it was considering testing of incoming flocks prior to slaughter, but it abandoned this in the proposed rule setting concerns over the cost of such testing to industry. Multiple expert bodies, including NACMCF, consistently support the importance of pre-harvest measures in controlling *Salmonella*.

And CSPI's 2021 petition and the principles of the Coalition for Poultry Safety Reform urged a framework that encompass supplier verification, extending regulatory review

of pre-harvest food safety controls.
We continue to urge FSIS to incorporate regulatory approaches to ensuring that best practices are used on farm in the final rule.
Next slide.
Regarding component two, our topic today requiring statistical process control.
This is an important advance in food safety what USDA has proposed, and this approach is also consistent with recommendations by NACMCF. The proposal builds on existing HACCP requirements, and it also seeks to address deficiencies in current implementation of SPC, of current plants not performing proper SPC.
This model and approach is already incorporated again into some private standards, retailers requiring it of their suppliers.
We also support the work USDA has done to include plans for supporting implementation by very low volume and very small establishments, including providing laboratory services free of charge.
Next slide.
But the true cornerstone of this proposed rule is component three, the enforceable product standard and FSIS has proposed a standard that incorporates both the level of *Salmonella*, in this case, selecting 10 cfu per milliliter or gram depending on the product, and *Salmonella* serotype opting for three serotypes of concern for chicken and three for turkey based on an analysis of predicted virulence and epidemiological data.
And now, broadly, a product standard that incorporates both levels and serotypes is a step forward, in that it will be risk based and it will be enforceable and in that regard it's aligned with CSPI's 2021 petition request and also consumer expectations.
And by that I mean that consumers expect that when USDA or a company identifies a product that contains high levels of forms of *Salmonella* that have caused a large number of illnesses and outbreaks, that that product won't pass into commerce.
And that is what this standard does.
The rule should also drive positive behavior in food safety best practices. By including serotypes of concern, the role would encourage innovation in pre-harvest best practices like vaccination and the enumeration element of the standard will incentivize best practices in the plant designed to drive down levels of *Salmonella*.
Now, we heard the argument on Tuesday that an enforceable standard would somehow prevent companies from testing for *Salmonella* or investing in controls.
That is not what happened in the case of *E. coli* and ground beef.

Where USDA has been consistently verifying that standard, and it has driven companies to test extensively and invest in control measures. Now granted with *listeria*, which also has a product standard, USDA tests only very sporadically and that seems to have led to some companies sticking their head in the sand and hoping that no one catches their violative product.

So a key lesson from this is that USDA will need to independently verify the standards for them to have the desired impact.

We also heard opposition to USDA's legal authority.

The Poultry Products Inspection Act gives USDA the authority to ban meat that is tainted with high risk pathogens.

It is the same well established authority that they have used before under the Federal Meat Inspection Act to ban *E. coli* and ground beef.

This is not a case where there is any ambiguity that would require USDA to fall back on Chevron deference. And if this is obvious when it's obvious just from asking a reasonable person, should the USDA put its mark of inspection certifying the safety of a product

on a product that's loaded with *Salmonella*. that's been a leading cause of outbreaks and they're going to tell you the obvious answer is no. This is not ambiguous.

But if poultry companies or trade groups want to fight to ship out product that is loaded with high risk *Salmonella* so that consumers will buy it and be none the wiser, then that is a fight that they are free to take to court.

Next slide.

If the new standard is flawed in any way, it is that it's too narrow and one huge omission is leaving out Infantis as serotype of concern. Infantis is now a leading cause of outbreaks in poultry, causing the second highest number of illnesses linked to chicken outbreaks between 2017 and 2021, according to CDC's latest estimates.

Yet it is not on USDA's priority list because, until recently, it was relatively rare, a rare cause of human illnesses and not likely to result in hospitalization or death.

And it's meteoric rise was due to the emergence of a virulent multi-drug resistant strain, that was first detected in travel associated cases in 2012, but did not receive much attention from regulators or industry until CDC announced a deadly multi-state outbreak in 2018.

Unfortunately, it's rise has been so swift that the databases used by USDA to understand virulence by serotype, may not actually include the virulence factors specific to this emerging strain.

Likewise, the weighting of epidemiological data from recent years may not have been sufficient to adequately assess the prolific rise of this emerging pathogen.
So you, and in addition, USDA failed entirely to consider antibiotic resistance in its analysis, a factor that also causes this strain to pose a greater risk.
So we urge USDA to reconsider its approach to Infantis to better account for the unique nature of this emerging strain.
Even with Infantis included, only a fraction of illnesses potentially caused by chicken is covered under the current rule because it will not include additional strains like Blockely, Banderup, Heidelberg; which were all leading causes of illness tied to chicken outbreaks in recent years.
We urge USDA to extend the standard to cover additional risk from these serotypes, one way to do this would be that instead of requiring a serotype of concern and high levels, that the presence of either a serotype or high levels would be sufficient to show a violation of the standard. Such an approach will also help account for the inevitable lag as new serotypes potentially emerge, because the role will cover high risk contamination regardless of serotypes present. Next slide.
And I want to close by saying, you know, USDA has often said that Americans have the safest food in the world, and I can tell you American consumers do not feel that we have the safest food in the world.
We only need to look to Europe, where coordinated farm to fork control programs have been in place for decades, covering every food safety step from vaccination to enforceable product standards, and see how these standards have led to stunning declines in *Salmonella* illness.
While we continue to be poisoned by our food at the same high rates, and we see that and it starts to look like 'safest food in the world' is just an excuse for defending a status quo that's not working for consumers.
But, we can agree that Americans should have the safest food in the world. Food that we can be proud to produce and confident to eat. And this proposed rule offers us a path to getting to that outcome
and we are looking forward to seeing it finalized.
Thank you.

Bailey, Shayla - FSIS 26:43
All right.

Thank you, Sarah, for your perspectives and your thoughts.
So next we'll hear from Rosanna Bauman from the American Pastured Poultry Producers Association.
Rosanna, you'll need to push the mic button to unmute.

RB **(PAUSE)**

Rosanna Bauman 27:35
Here we go. Alright. I'm sorry.

Bailey, Shayla - FSIS 27:35
There you go. Thank you.

RB

Rosanna Bauman 27:38
I didn't have my, it didn't block out my mic button. Thank you.
Alright, I'm Rosanna Bauman.
I'm a farmer and processor from Kansas.
I'm here today representing the American Pastured Poultry Producers Association.
I'm not a doctor or a researcher, like a lot of the presenters have been the last couple of days, but I am a processor. I am in the field every day and I can gut chicken in 1 1/2 seconds.
Which I feel makes us qualified to speak to this matter. The American Pastured Poultry Producers Association represents about 1,000, a little bit over 1,000, producers of poultry across the United States. Many of them also are their own, do their own processing. Some of them are exempt.
Some of them are fully inspected. Around the nation, we only have about 30 plants that are considered very small, traditional and an even lesser number of those, we are trying to get a hard number on if it, is a fee-for-service processing.
Next slide please.
The fee-for-service poultry processing is a sub category of inspected processing plants in poultry that has been entirely overlooked and ignored in this proposed rule.
There's very few of us across the nation, but what I think the question from yesterday that got misunderstood is that there is no technical category for custom exempt poultry inspection. Because of the Curtis Amendment in 1967 just said meat.

It didn't specify poultry, so therefore what some people may not be aware of, unlike the red meat plants, I cannot process custom exempt poultry in the same plant as inspected. So, if someone comes to me only wanting to have their birds processed, that they raise themselves to take back home to their home freezer, they have to receive the inspected stamp.

Next slide here. One of our big concerns with this proposed rule is there is no acknowledgment of this fact or for fee-for-service processors. We really have a, I believe that the FSIS, has a legal obligation to put in an exemption for poultry not intended for commerce, so that we are not testing poultry that is never expected to go into the food chain at all. Next slide.

There's the other thing that would be unique to fee-for-service plants, is what to do with birds that would be tested and considered adulterated.

Obviously there's two options, currently they give you for fully cooked or you can destroy them.

Obviously there's very, very few access to cooking facilities for small plants that would do anybody's fee-for-service fully cooked product.

Then we would like to propose an additional option for adulterated product to be returned to its owner. Since the plant itself owns very few, if any, in this category of poultry that's being tested.

We feel like there's a big legal risk to the fee-for-service plants if we have to condemn poultry that we do not own, did not raise.

We wouldn't be able to find any insurance to cover this loss, and obviously an uninsured plant is not going to be in business either.

Next slide please.

This one here is, we're not going to go through this whole flow chart.

We had some of our members put out a flow chart of how this proposed rule can affect the operations on their plant.

In short, what this points out is this proposed rule did not take into consideration at all the impact that this would have on fee-for-service and very small plants, specifically.

Next slide please.

The financial impact, it's not being dramatic at all to say, that if this

if this rule goes into effect as proposed 80% of the fee-for-service plants in the nation would close immediately. I'm not saying that

just to be dramatic, it's the fact we've talked about this among ourselves.

It's a risk we can't take and it's a risk that has not been calculated in there. The lost industry, just by one, we've doing some internal calculations here. Just by one of our fee-for-service plants in the United States closing, is an $8 million loss to industry in product, $8 million worth of poultry that's not hitting the market.
Um, there's no competition among us, if one closes, nothing else rises for good reason.
$8 million is half of the total proposed cost of this entire initiative, let alone the lost value to the industry is $2.4 million.
That's only for one plant.
Say we have 10 plants go out.
You're at $80 million.
It's clearly not been calculated or considered in this proposal. Next slide please.
(The testing frequency) has been intentionally ambiguous
and obscured in this proposal. It's unclear at all, although referenced that the testing frequency would be staggered similar to the existing *Salmonella* Performance Standards. The testing frequency, as done in the existing standards, is very unfair and unrepresentative of the actual volume that enters commerce.
Next slide.
So currently, the small plants are tested (unintelligible, break in recording) more than some of the larger counterparts.
This is just on a regular basis.
This is not if those small plants are in category three. It's literally 30,000 times more frequently than the larger plants.
And these sound, they are astronomical numbers, and I know they don't sound believable.
There is possibly some correlation, to be said, we the where are we testing.
We're not testing, we're talking about how come this plan hasn't been effective. The percentage of poultry that is entering commerce, the focus on testing has been completely on the smallest subset of poultry that's entered commerce, it's definitely not been an accurate or fair or equitable sampling representation of product
that entered commerce. Next slide please.
So our organization definitely appreciates some of the improvements. I guess I would say that have been suggested here.
We really do.
We really do support the move to enumerated testing, as opposed to the prevalence

based testing. Prevalence based testing gave us virtually no data to make informed decisions.
It did give you a little bit, you couldn't fine tune an operation
at all. So enumerated testing in sets makes sense.
It also makes sense why component one was struck down, since USDA didn't have any legal authority to reach into the live bird category. However, we would suggest the FSIS would work with a partnership with APHIS to get the hatcheries enrolled and monitoring on the *Salmonella* at its source.
Next slide please.
But.
Trying to follow along in this logic in the proposal and in the National Register is really difficult. So, we have the problem that consumer illnesses from *Salmonella* have not reduced in the last. Since this *Salmonella* initiative program has become a part although the *Salmonella* at the processing plants have
been reduced by 50%.
So the response to that is from the FSIS, is they are hypothesizing that to declare an endemic pathogen, an adulterant legally, will help reach the goal.
It's been stated that the fact is consumers are innocently but ignorantly under cooking poultry, and therefore; it's not their problem that they're getting sick from undercooked poultry.
So the converse of that fact then implies that the processors are intentionally contaminating the poultry. If the consumers are innocent in their handling of it and in their cooking of it, then who's to blame?
By that, and that is a legal burden that I feel sets a lot of processors up for consumer lawsuits.
By merely doubling down on processors and saying look, public consumer illnesses haven't changed, it must be the processors. They've reduced it by 50%, but somebody's still getting sick.
I feel like we've really lost sight of the goal and that's reducing the consumer illnesses.
Next slide. So, we keep beating this dead horse at the at the point of processing when there's so many other steps in the, in the chain. I don't wanna use the term insanity, but we're doing the same thing over and over again.
We're expecting different results.
Enumerated testing, additional testing; when public illness has moved zero or next to

zero, I shouldn't use that important grammatical term in that way, but public illness has moved zero with a 50% reduction
at the point of processing indicates we're barking up the wrong tree. Next slide.
And I think one thing to consider from this quote here.
Remember what we're talking about producing.
It's a raw product.
And I know, next slide please.
I know everyone at the USDA FSIS has worked many years on this.
We've been aiming for it for a while and I'm sorry to say, I think we've completely missed the target with this one.
We've lost sight of what the goal and the target actually is, and that's reducing consumer illness, and we're trying to find the most effective way. None of us, the processors are not trying to kill their customers.
Nobody wants to see sick people, but we have to remember what product that we are providing. Next slide please.
So curiously enough, I'm not well versed enough on the history and have not been able to find out this, why the poultry stamp says wholesomeness and the beef stamp does not.
Um but, I think we can agree that that stamp gets put on when we're in this project, in particular is talking about raw poultry.
Ten colony forming units per milliliter is not considered loaded with a pathogen that is endemic to the species, to the product that it's on and it is still a wholesome product, but it is a raw product.
Wholesome does not indicate that it's ready to be eaten.
It does not indicate that it should be eaten raw or undercooked or anything and so, I feel like that's the goal that we've lost sight of it.
We're trying to raise a enforceable final product standard, that it doesn't even, the shoe doesn't even fit. So, there's different stamps, I guess from the one that the USDA enforces. Some are for wholesomeness, some are for quality.
You see here on the screen we have two examples of quality stamps.
That's an organic stamp.
That's a grading stamp. USDA Prime Choice select.
We would propose that, maybe we should look at this differently.
We have different consumer groups out here.
That some of them want, that poultry is the most widely consumed in America

because it's the most affordable natural protein.
We have consumer groups that wants their chicken more sterile because they habitually undercook it.
They want something that is safe to feed to immunocompromised people. We have other consumers that don't want their chicken chemically sterilized because they view their food as medicine.
And that's why I think if we would look at this problem,
and separate the wholesomeness from the quality stamp.
Perhaps we need to make a new quality stamp? Emphasized, put the word raw on underneath, on top of in bigger letters on our labeling standards. That this is raw. If there are consumer groups that need sterilized meat, that's guaranteed not to make them sick, let's create a quality standard that those folks can buy with confidence. Instead of having to wonder which retailer to buy from for the most safe meat they can look for the seal of quality and sterilization from the USDA. Next slide please.
A single enforceable product standard already exists.
That's our stamp of wholesomeness.
The industry produces a wholesome, raw product.
The *Salmonella* Performance Standards have helped us gauge it.
We're not saying that we don't need any testing.
I appreciate the information that our testing has done.
We can keep striving to it.
But, when the stakeholders are so far apart on this proposal.
Some invested stakeholders think this rule hasn't gone far enough.
Some invested stakeholders think this rule is going too far.
That's pretty clear. When my business has that, it means that when my stakeholders are that far apart on my proposal, it means I need to go back to the drawing board and find one that's completely different because we were trying to find the solution in the wrong place.
Thank you, Shayla. I'm done there.

Bailey, Shayla - FSIS 43:01
Alright. Thank you, Rosanna.
We appreciate your thoughts and your perspectives. For our third presentation, we will hear from Matthew Stasiewicz, who is from the University of Illinois.

SM

Stasiewicz, Matt 43:17

Hello all.

Thank you FSIS for giving me the opportunity to share some thoughts. I hope I'm coming through clear, and someone will tell me if I'm not. So, what I'm going to be talking a bit about is, is my perspective from the University of Illinois, here. Largely presenting a bit

of a project that we talked about previously at IFP last summer where we started to look at relationships between

total plate count reduction and *Salmonella*

measurements in processing. How that can provide some insights on statistical process control for controlling *Salmonella* in raw poultry and maybe opportunities to ensure that this framework allows for continuous improvement in the industry. Next slide.

And so my main comments here is that,

at least from my perspective, this existing SPC monitoring method does plausibly demonstrate sanitary dress.

This brief summary of something being capable of achieving a one log reduction from rehang to post-chill.

In total plate count, I think what's also relevant is that, at least to the best of my knowledge, there's no public peer reviewed data suggesting that this specific metric, achieving this one log reduction is meaningful, related specifically to controlling risky *Salmonella* and finished products. Taking as a starting point for that, even this, you know above 10 cfu per gram or minimum in finished product.

And so I think what that suggests is while that, there's certain capable, sanitary dress is perhaps necessary, there's more that would be, then that's not sufficient for full species for safety.

And so I think it's important that as this moves forward, that there's additional guidance on what would constitute an adequate alternative program. So that companies could, and the broader research establishment could, continue to research, innovate and continuously improve how they're using a full suite of statistical

process control and other data analytics tools for continuous improvement to drive safety improvements and that perhaps gets stuck in what was described here as a as

a safe harbor.
So next slide.
So one piece.
These are just two pieces of data that have been published by other researchers.
Not my group, showing really, I think a lack of obvious correlation to finished product *Salmonella* and bio-mapping data.
So the panel on the left was a paper that was looking at correlations between aerobic plate count Enterobacteriaceae and then *Salmonella* measurements and incoming feather removal, viscera removal and carcass wash and showing a
cross those eight panels, relatively weak correlations between the indicator organisms and *Salmonella*.
And then the panel on the right was data presented from a slide deck that I found on the FSIS website.

Also, that same group showing just changes in *Salmonella* prevalence and count throughout primary and secondary processing. Where the broad trend is as has been said, right *Salmonella* prevalence, right, moves down from receiving to post-chill.

When you get to dunking the bird down, prevalence pops back up and then levels, while still small of *Salmonella*, also do increase, right?
Suggesting there's a bit of a disconnect between the reduction achieved through post-chill to what happens during the other secondary processes and so I think there's just more opportunity for improvement. So next slide.
So, what
I want to start talking through is some preliminary results, from an academic project using some industry data that shows both how we think the existing methods would apply to the data that we had, as well as opportunities that where research could go beyond.
And So what this plot is showing is a year of data for a process that was demonstrably capable of achieving that greater than one log reduction.
So that this plot is showing just the difference between
rehang and post-chill in log scale. Where every data point on there is below the minus 1 log mark, meaning that everything is meeting that one log reduction.
And if we calculate according to the metric, the CPL-SSM in that Safe Harbor proposal, they are more than achieving the point for threshold that you can get the

mean from that data. With my math on the slide the mean, the deviation, that lower specification limit.
Do the math. In this year's worth of data they're meeting the standard.
And then looking at the variation in the data that you see, there's been some points that are also in this plot.
Set as orange.
And if you go to the next slide, they were set as orange because what we applied were the eight typical rules for statistical process control. Where you take a run chart, you turn it into a control chart where you take the mean, the standard deviation. You have that 6 standard deviations from the mean, of three standard deviations from the mean in each direction, and based on patterns in these points that are shown in on the right panel, you can identify early warning of process shifts that might trigger, hopefully, action to bring your process back in control. So, for example the top left would be one point beyond the three standard deviations from the mean. Which is like that one point that's identified in the left most in the graph.
Or maybe another zone where you've got a section of points with lower variation than expected, which could suggest some other issue in the process.
The point being here is that there are many methods for a run chart of data where you plot a metric like a one log reduction to extract systematically early warning of shifts beyond just meeting a criteria. Like a specific one log reduction capability and that could provide more information potentially to take action.
The real question is, does that action meaningful relate to outcomes of interest? And so next slide.
And so here I recognize this is a bit busy of a slide, but what we tried to look at was comparing for the same time frames. The top right panel in this plot is what you've seen before.
That one, that difference between rehang and post-chill over time. And then the bottom panel directly below it, is a run chart of results from parts produced on the same days when they line up in a column in the same days, from the same lines. Where the vast majority of the green open circles were negative samples. There's a few blue circles.
And then those very few orange dots in the bottom plot are cases where *Salmonella* was innumerable and based on the method that was being used, meaning above 10 cfu per milliliter of rinse in the parts.
So this that's what that panel shows. The left two panels are, the bottom left is the

same data overtime for ground product produced in the same facility at the same time. And then the top left panel was also a difference chart, but in this case between pre-scald and post-chill.
So a longer span of the process, where in this case there was on average over a seven log reduction and outliers additionally flagged.
Next slide will bring up some annotations that show what I think is maybe the obvious question, which is those very few cases where product, finished product parts and ground, had above the level of-- was in the level of quantification above 10 cfu per gram or milliliter.
Don't necessarily correlate either to cases where we weren't achieving the one log reduction or cases that were obviously flagged by any of these statistical process control rules for outliers.
In total point count reduction for either of the two process stages. And so it just suggests that, you know the process is reducing microbial load, but it's not necessarily strongly related to the reduction in risky *Salmonella*.
As even evidenced by some of the reasons to identify those in the component three, so next slide.
What I think this means, is there could be a value in additional guidance on what an alternative program could require if companies then wanted to innovate and move beyond and do more than just that safe harbor. And so, this was already summarized by the first presenter, right? And I bolded some of those, what the key metrics were; statistically meaningful data, benchmarks to evaluate the metrics data and otherwise to define the statistical methods, right.
The bones of my evidence, right, and you saw those bullet points earlier.
And then this idea that establishments that incorporate the
proposed plan and metric wouldn't be required to provide additional scientific or technical information to support their methods.
I suppose what I'm concerned about is, it's not then clear what support would be sufficient to do something that's a deviation from the safe harbor. I worry that that might then create a framework that incentivize maybe a minimum necessary program and stifles moving beyond to do something that would be more me robust.
And in particular, an open question is how might a company incorporate other measurements beyond just microbial monitoring data that could relate. That could be measured in real time, something like a specific process performance metric that comes off a gauge or a data logger, that could then be used to trigger real time

improvements that proactively manage *Salmonella* contamination.
That's just not how clear how to work that into this this piece. And then I think there's a way in some of these analysis to show how that process of learning from the microbial data.
Tracking it and analyzing it could identify better targets, which I'll show next.
So next slide.
So in this case, one pieces could even more be done with the statistical process control tools.
So I've showed you these run charts before where we had flagged points as outliers. One piece is even in the existing framework of tracking one log difference; we, there could be potential to use these rules to flag outliers, but they are actually a lot more complex than typical statistical process control.
Textbooks and guidance, for example in microbiology, right? What we're interested in, we're calling a bad flag in orange would be if your log reduction was too low, right?
The box.
The box is near the top of the runs, where you're getting less log reduction than you require, it wouldn't necessarily be a problem if you get more log reduction than you would typically, right? And then there's a whole set of other rules that might show differences, like less variation.
If companies were to move forward with statistical process control, they would also have to adapt those techniques to be relevant to microbiology, where the directionality really matters.
More log reduction is the goal.
Less log reduction is the problem. Microbiology also has issues like limits of detection and censoring. If you have a product coming in with a relatively low load at the start of a process, you can't measure very much log reduction because you hit the limit of detection of your assay.
And so there needs to be methods to adapt these classic process control tools to the realities of microbiology in the class of these contexts.
Things which we've been working out, and I think the industry could potentially continue to improve on.
Even with this requirement to monitor and start the process based on the proposal.
The other pieces is could we find better indicators, and that's on the next slide.

There's an there's an opportunity that potentially more analytics could do better, right?
So this this idea of when you'll be adopting, this SP, this data set
for process control metrics to risky *Salmonella*, we didn't find anything obvious in that run of total plate count reduction that explained the few rare, high-level events of *Salmonella*. And so then, one could ask could we analyze the data in different ways? Find different features from the microbiological data that could be a better target and in this case using machine learning and all the different ways that we could slice and dice the data.
Really, the one feature that popped out was in the very rare cases where birds were processed after four or more days, that was meaningfully associated with a higher risk of *Salmonella*. Right, where the prevalence risk in that was going, you know, five out of the seven samples.
That were so it's a rare occurrence, but it is associated with a higher risk of a positive, suggesting maybe that that could potentially be a useful target to incorporate in a process control framework.
I think what that broad paradigm suggests is with routine microbial monitoring data being analyzed and assessed, the system overall could identify better targets for improved process control, and particularly what if they were real time measurements. What if they were something that could be proactively adjusted rather than waiting for lagging indicators of microbiology?
That could potentially be very powerful.
Next slide.
And so hopefully, through this last few slides, as a vignette, I hope I've shown that beyond the one log reduction capability, there are some more comprehensive statistical process control analyses available that could systematically identify other times in the data set that might require action of features that might require action and could potentially be built into that program for response, in that, as that could continue.
Further research could identify even better targets.
I think the other challenge is that, at least to my reading of the rule, is some of those more advanced approaches don't neatly fit into what was specifically provided into this guidance. And I just want to be careful that the guidance doing one necessary piece isn’t stifling innovation on what might be done more robust.
So my next slide is just to wrap up of what I've said.

Basically, again, here I think the current proposed method does possibly demonstrate that one log reduction.
There's a question if that directly relates to finished product *Salmonella*.
And with some better guidance on what would be adequate alternative programs that could do more.
That could better support innovation and continuous improvement in developing more statistical process control metrics ultimately so that.
There's a framework for emerging learnings throughout the poultry safety community to be used by processors and not advertently getting tripped up by a proposal.
So that's what I have. Thank you.

Bailey, Shayla - FSIS 59:20
Alright. Thank you, Matthew. We appreciate that.
Our last presentation is from Ashley Peterson from the National Chicken Council.

AP

Ashley Peterson 59:39
Thank you.
Good afternoon.
My name is Ashley Peterson with the National Chicken Council, and we appreciate the opportunity to discuss the proposed statistical process control component included in the proposed *Salmonella* Framework. Next slide.
There are a few items I would like to discuss today, including: how industry uses SPC, raise a few concerns regarding some of the proposed SPC requirements, outlined educational needs, and proposed a few questions. Next slide.
First, let me start by saying that industry supports a process control standard.
But we have several concerns regarding the language included in the proposed component two.
A successful pathogen reduction including *Salmonella* starts with strong process controls.
It is critical that the updated regulations provide the best path for industry to control their process and have the right data to verify their efforts.
Statistical process control, or SPC, is a robust tool used by many in the industry to monitor their process and ensure that these processes are functioning as intended.

Samples are collected and results are monitored on an ongoing basis, watching for trends that may indicate there is or could be an issue with the process.
This slide, though it wasn't as good as Matt's slides, demonstrates what an outlier is on the left versus a trend there on the right. There is a significant difference between these two, and not only what they mean, but how industry responds.
This is a very important point that we believe is inadequately addressed in the proposal.
According to the proposed *Salmonella* Framework, FSIS is proposing to require establishments to implement written corrective actions, including a root cause assessment when microbial monitoring results deviate from a predefined target criteria. The agency further states that an establishment must have documented corrective actions and perform a root cause analysis
of any deviation in target change.
This is inconsistent with the overall intent of SPC and how industry responds to information.
A single outlier, as demonstrated on the left chart, which appears to be what the agency is referring to in their proposal, would not trigger a root cause analysis or corrective action. Further, if this does become part of the new regulatory requirements, this would result in hiring of additional staff in order to attempt to solve a problem that, truly, does not exist.
Hiring additional staff was not included in the agency's cost benefit analysis. A trend as demonstrated on the right, unlike an outlier, would most certainly result in a root cause analysis and corrective action. It is important to recognize the difference between the two. The proposal, also largely overlooks the second part of the production process, which serves as an important location for both potential contamination and successful intervention.
This also needs to be addressed in the proposed regulation.
Next slide.
It is critical to acknowledge that while tracking and responding to this information is important in maintaining control of a process, test results are not instantaneous. An a best case scenario sample results will be available within 6 to 8 hours of sample collection and that will be only for establishments with a laboratory on site, which is not common across the industry. In most cases, samples must be sent either to a company owned offsite lab or a third-party lab.
As mentioned, most establishments do not have laboratory capacity on site, meaning

samples must be shipped further delaying time to results.
I say this, because it is important to understand that the results are not received in real time, though exceptionally valuable to monitoring and reacting to our processes.
Next slide.
Regarding sample frequency, FSIS finalized and one for 22,000 sampling requirement at both pre-chill and post-chill in the Modernization of Poultry Slaughter Inspection final rule from August 2014.
In that final rule, FSIS does not prescribe the pre-chill sampling location, but the proposed *Salmonella* Framework will require establishments to sample at rehang.
Does FSIS plan to modify the current, the existing regulations? Or will establishments that participate in the *Salmonella* initiative program now be required to sample at three locations: rehang, pre-chill and post-chill. If the agency plans to require a third sampling location, this was not included in the cost benefit analysis and could potentially put companies at a competitive disadvantage, who will now be required to take and analyze additional samples. Further, now that the agency has 10 years of data from industry at a sample frequency of one per 22,000, what has the agency done with this information and what benefits are there continuing to sample at this frequency? We encourage the agency to reevaluate this sample frequency requirement.
Next slide.
As mentioned on the last slide, to participate in SIP and the new poultry inspection systems, establishments are already required to submit both APC and *Salmonella* testing data to FSIS. In the proposed *Salmonella* Framework, FSIS would now require all establishments to, and, I quote, submit their microbial monitoring sampling results to FSIS electronically.
Will this be a new requirement for all establishments?
What will FSIS do with this information and how will it be kept secure?
Since we do not provide our HACCP plans to the agency, why would we provide this information to the agency when implant personnel have full access to all of our records at any time?
Next slide.
In the proposal, the agency states that it expects a reduction of at least one log between sampling locations, which includes the new sampling location at rehang.
What if it establishment does not start with one log every hang? If an industry is now expected to demonstrate a one log reduction, how will this incentivize

establishments to continue to implement successful and impactful control measures prior to rehang moving forward?
Instead, we suggest that the agency allow establishments to determine its baseline at rehang and establish an alternative target reduction.
Instead of a log value, next slide.
According to the agency, FSIS will require microbial monitoring results and documented corrective actions to be included in the pre-shipment review process.
As part of a HACCP Verification Task, implant personnel are verify that an establishment completes the pre-shipment review process before product enters commerce.
In many cases, chickens are processed and ready to go into commerce within hours.
As previously discussed, indicator organisms are not available in real time.
Sample collection, shipping and analysis can take anywhere from 24 to 48 hours. If microbiological monitoring results are required to be included in the pre-shipment review process, all product produced by the industry, all 46.4 billion pounds of ready-to-cook chicken per year, would have to be placed on hold until the sample results are obtained and incorporated in the pre-shipment review process.
This would have significant and costly impact on the industry. Another component that also was not considered in the agency's cost benefit analysis.
Next slide.
Industry needs guidance and education from FSIS regarding SPC.
This information should be uniquely tailored to an establishment based on its size.
Further educating FSIS personnel on how to interpret and appropriately react industry data and or actions will be critical in the success of an SPC program.
In summary, process control programs should help an establishment implement sanitary dressing procedures to prevent contamination, implement effective decontamination and antimicrobial interventions, properly assess microbial testing results, include results for indicators of process control or at any point during slaughter and use these results to drive continuous improvement in the process.
Next slide.
We have posed a series of questions throughout this presentation, and we feel that it is valuable for the agency to consider these in order to make component two a successful tool for both the agency and the industry. Some of those questions include, can you expand upon the agency's interpretation of SPC? What are the agency's expectations regarding outliers versus true trends with indicator organism

test results?
And how is the industry expected to react to both?
The agency is requesting information be submitted on an ongoing basis.
What steps will be taken in order to ensure the security of this information and how will the agency use this data?
Will the agency amend existing sample collection requirements and reporting of information to FSIS?
How can the industry achieve a one log reduction if we do not have one log to reduce?
How can an indicator organism, which are not real time, be included in the pre shipment review process?
Those results could take an industry, take the industry 24 to 48 hours to obtain. And finally on education, how will FSIS educate their staff, including implant personnel: EIAOS, FLS, IICs, et cetera. on how to interpret an establishment's SPC program and reactions? And finally, how will FSIS educate an entire industry, regardless of the size of the establishment, on how to implement and execute a successful SPC program?
We're hopeful that that FSIS will provide some insights into these questions today.
Without this information, it remains a challenge, and in many cases, nearly impossible to provide meaningful feedback on the agency's proposal, last slide.

Lastra, Julie - FSIS 1:10:17
I'm showing that this is the last slide.

AP

Ashley Peterson 1:10:17
Maybe there isn't a next slide. OK.
Well, in conclusion, industry supports a process control standard, and we would like to work with the agency to make the necessary modifications to the proposal to make component two both implementable and actionable. We believe that a robust SPC program coupled with an enumerative performance standard will have the greatest impact on public health, while allowing industry to provide safe, affordable and abundant supply of chicken both domestically and around the world.
As stated in the proposal to achieve the healthy people 2030 target, *Salmonella* illnesses must be reduced by 25%. The agency's own risk assessment indicates that a

hypothetical aerobic count reduction standard could achieve a 25% reduction in *Salmonella* illnesses attributed to chicken if microbiological criteria were based on a two and one/half to three log reduction or no aerobic count tests exceed 10 cfu per mL at the post-chill location.
This further underscores the importance of a robust SPC program.
Thank you.

Bailey, Shayla - FSIS 1:11:29
All right.
Thank you, Ashley.
That concludes our stakeholder presentation.
So I wanna thank everyone who shared their perspectives with us today. And we're gonna move into our discussion portion.
And I know that Ashley at the at the end of your presentation, you did propose some questions or need some input from FSIS on some of those points that you raised.
So I am gonna open it up to the FSIS folks and see if maybe.
Some of our, my colleagues can weigh in on it.
I don't know, Rachel. If you wanna get us started, yeah.

EF

Edelstein, Rachel - FSIS 1:12:10
Sorry, I'm sorry, Shayla.
Did you want to start with the ones that Ashley raised at the end? Yeah.

Bailey, Shayla - FSIS 1:12:16
Yes, please. Yes.

EF

Edelstein, Rachel - FSIS 1:12:18
And I think a lot of those are things that are really good comments that we definitely need to consider.
I mean, as far as like the taking corrective actions and pre-shipment review, I think FSIS was thinking generally. About, you know, making sure that the establishment is making the necessary changes to the, you know, to addressing things that happen. That you know that aren't, that indicate that there is a um maybe a problem. Versus and taking into the results you know, taking the results into account when possible.

As you know, as they relate to.
I'm sorry I can't, there, there's Ashley. I'm having trouble seeing everybody.

AP

Ashley Peterson 1:13:05
I'm here.
No, and I appreciate that.

AP

Ashley Peterson 1:13:08
I think clarification on that would be really helpful, because as it reads today, the pre-shipment review requirement includes the data and corrective action. And if it's more of a, our process is in control um sort of statement included in pre-shipment review. That's a very different interpretation and we would certainly appreciate clarification on that.

EF

Edelstein, Rachel - FSIS 1:13:29
Yeah, yeah, yeah.
And then the one log reduction is not something that was, that that's required.
I think that was just some discussion of where the statistical process control is.
It wasn't something, we didn't mandate a one log reduction.

AP

Ashley Peterson 1:13:48
OK. And that would be also helpful to clarify again. We definitely know, and we want to demonstrate a reduction.
It's just we want to, if we don't have a log, I don't want to create an opportunity where we have to have a log in order to reduce. Because if we started at a half a log at rehang, which would be excellent, then you know, can we reduce it further from there, so just some clarity on that would be great.

EF

Edelstein, Rachel - FSIS 1:14:12
OK.
Yeah, I think it's a minimum benchmark when using log value monitoring.
But yeah, we can clarify that.
And what were some of the other things that I was going to?

Oh, here we go.
I mean that, and you raise, you raise good questions about SIP versus the new um, these proposals, I don't think that we've gotten into. I don't think we fully considered that.
And the question about what we were going to do with the data, I know that was something that we um and we explained it in the Federal Register in the preamble. Where inspectors would continue to review the data in establishments, but we'd also if you know, they would be sent into headquarters, so that headquarters would evaluate national trends to determine the efficacy of the revised process control requirements and to inform FSIS decision making concerning our verification sampling.

AP

Ashley Peterson 1:15:26
OK, and that would be helpful to clarify, too. Cause, I think having implant personnel look at the information and interpret it and essentially say "OK, you're doing what you need to be doing". Is that's what we would hope for. As long as we're doing what we need to be doing, but we wouldn't want to send this in for the agency then to say, "Oh no, you're actually not doing what the implant personnel said you were doing correctly." So, we wouldn't want to get into that sort of situation.

EF

Edelstein, Rachel - FSIS 1:15:52
Right. And we could,
I mean it that.
Yeah, I mean, I think it was basically, what I read from the preamble, was more like where FSIS is looking at overall trends.
But yeah, I see what you're saying.
That's something that we could further clarify.
That's a good comment for us to consider, too.

AP

Ashley Peterson 1:16:10
And the only other one, Rachel, if you don't mind speaking to, is this interpretation of SPC, which is the first question on that slide. Given that there is a difference between an outlier, meaning a one off occurrence, versus a true trend, which would certainly prompt industry action.

And doing that, you know assessment and potential corrective action, I think it would be helpful, if the agency agrees, that those are two different things, two different scenarios.
That if you could provide some clarity in that, because the way I read the proposal is that any deviation is now going to have to result in some sort of evaluation and corrective action. Which again, as I mentioned in my comments, could potentially have us running all over the place trying to find out, you know, do a root cause analysis on an outlier when it's just an outlier and it's very different than our process trending out of control.

EF

Edelstein, Rachel - FSIS 1:17:15
OK. And I can't, I don't think I can give you a firm answer on that right now. I think that's a good comment for something that we would need to clarify, you know, should the rule go final. Something we should clarify in the preamble and in the guidance that we put out on monitoring, on process control.

AP

Ashley Peterson 1:17:33
OK.
Thank you. I appreciate that.

Bailey, Shayla - FSIS 1:17:37
Alright, thank you.
I appreciate that discussion and glad we were able to address some of the questions that were proposed there.
So I do open it up to the rest of our panelists, either on the FSIS side or those who presented today. If you have questions or comments for each other, or things you wanted to revisit to discuss a little bit further today with others who have presented or with the FSIS team.
I'll pause just a minute. You can feel free to raise your hand if you see that option.
Sarah, I see your hand up.
Please, please go ahead.

SS

Sarah Sorscher 1:18:17
Yeah, I have a comment and then I had a couple of questions for my co-panelist

Rosanna. The comment was, you know, consumer education hadn't been on the topic for today, but it came up during the remarks. And I just wanted to highlight that, you know both under cooking and cross-contamination are obviously huge issues and targets for consumer education. And USDA is working to update the Safe Handling Standards, has been working for many years as a separate process to what we're talking about today.

Consumer groups have consistently pressed for and elevated that effort, and we also participate in other education efforts and have partnered with industry groups on consumer education and welcome further partnership.

And I want to flag that none of the policies that consumer groups or FSIS have proposed is going to result in sterile chicken, right?

We're not going to relieve consumers of that responsibility of cooking. But, what we're looking to do with this proceeding is to make sure that we're using best regulatory practices to control risks from farm to fork, and the strategies that have been shown to actually reduce illness have all involved an enforceable product standard.

My questions for Rosanna were first, I know that you had to condense everything, so I was hoping to dig in a little bit more on couple of things you mentioned and one of them was this idea of plants closing and obviously we want to have a diverse, we want to have a diverse industry. We don't want small plants to close.

And I was hoping you could delve into a bit more, of this idea and what causes the closure?

Is it that you expect a large?

Is it the product standard or other elements of the rule?

And is it that you expect a large share of product will be violative, and so it's the cost of losing that product?

Or is it some other element or concern that that leads you your members to discuss closure?

That's the first question and the second question was just, I want to hear more about getting hatchery's MPIP monitored as a proposal that that you'd include in your slides.

And hopefully Rosanna's still here cause, I know she had a little one in the lead up to this, so she may have had to step away.

Rosanna Bauman 1:20:22
OK.

Bailey, Shayla - FSIS 1:20:23
Looks like she. Yeah. There you are.

Rosanna Bauman 1:20:24
Alright. Can you hear me now?
OK, good. Yeah. Thanks.

Bailey, Shayla - FSIS 1:20:26
Yes, we can.

Rosanna Bauman 1:20:27
Thanks for those questions.
Sarah, I had to condense things.
Obviously, one thing I maybe I didn't have a chance to highlight that I was hoping would I would remember to say specifically about the consumer education thing.
There's a few things that, that's not to say that there's zero consumer education now.
But I feel like it be well worth industry, the I should say, federal resources, not industry, but even industry resources in a massive consumer campaign because those have been proven to work. Specifically, campaigns like Smokey the Bear had. I'm in Kansas and we don't really have forest fires here and I even know about Smokey the Bear.
And that concept, more than just labels on products, obviously that's necessary.
That's needed.
We also know that nobody reads them, just like nobody cooks things properly.
This we don't have any, like, no, there's no formal training in our education system, even for food safety.
If everyone is a homeowner, home cook, everyone's a eater.
Our education system no longer has home EC.
You don't have any exposure to knowing anything about food safety, unless you

happen to go into food service.
So to clarify, that's a little bit what I mean by, not meant to pass the buck, but recognizing that our public has not had the opportunity to be educated and I believe that we, the nation, has designed public awareness campaigns very effectively in the past.
I think it could be done again.
In response to the plant closures.
Thank you for asking about that.
It's more of a risk, and a risk and investment standpoint. Less of we think that all of our chicken can be thrown out and now, now we don't have any products go out the door. But plant closures specifically, we've invested, you know, a lot in being able to achieve the log reduction, the *Salmonella* reductions, everything that we need to do. But specifically, the plants that I'm talking about, fee for services, we have like, we're 100% variable plant.
This program is designed for no variability. Statistical process control in the FSIS education documents about that statistical process control specifically states that it does not work in situations with high variability. So, one every producer has a different breed, a different hatchery, a different feed, a different size of bird.
I'm just dealing with a lot of variability there, so trying to get it to plug into a system like that looks nearly impossible. The extra time and energy that Ashley mentioned on behalf of this plant processor, I mean I gut all of my chickens myself. I don't have a lot of time to spend trying to navigate a clunky government website and get that system to work to plug in my sampling data. That back to the time to wait, you know, till your sample results are back, most of us are in rural areas. We're talking you know shipping time and delays to lab.
So it's a bunch of little things like that.
But the one thing that I think just makes us close our doors immediately and this is. I mean and I'm being honest here, we've had some plant owners that have qualified for some of these COVID era government grants and loans to help expand small plant processing. Some of them are sitting on their loan and grant money, afraid to invest it in their plant.
Just because they know that if this rule comes in, to invest in their plant and this could be like not necessarily in food safety, but like expansion freezers, whatever, if this rule comes into place, the legal risk is off the charts for me.
The by doubling down with this proposed *Salmonella* Rule, it as I mentioned earlier,

it clearly shows that USDA believes that the point of contamination is at the processor.
One, that puts me at a legal risk for consumers.
Two, that puts me at a legal risk for my farmers that I process for.
So let's say a farmer brings in their birds to me and it does process hot and I have to condemn it.
I am the one that's carrying the legal liability for that.
They would have a lot of legal president to support a lawsuit against me for condemning their product.
The alternative is that I would look for insurance to cover product of others that I do not own, that I would have to condemn.
Which I currently have insurance coverage for,
like if my freezer goes down or my cooler goes down, and I have to throw out other people's product. My insurance policy covers it. Insurance policy does not cover issues, what they consider organic or natural, like microbiological contamination.
That COVID pandemic made a lot of people write in extra clauses into their insurance things.
So a scenario like this to where I would have to condemn a customer's chicken because of contamination.
Umm.
I can't get insurance coverage for it so that legal risk, my margins are razor thin. That legal risk is enough to be like, I'm not even gonna go to that first condemned thing with my customers, because that's a business ending situation right there.
But hopefully that helped clarify a little bit.
But ask again if I didn't address what you had for your question.

SS

Sarah Sorscher 1:26:40
That is helpful.
And then my last question was about hatcheries and trying to get them MPIP monitored.
I was wondering if you could explain a little bit more about that.

RB

Rosanna Bauman 1:26:50
Yeah, I'm not gonna be the best person to give a lot of detail on that.

Some of my colleagues at APPA work very close in hatcheries and very closely with hatcheries.
This is an existing program with APHIS that I believe is voluntary right now, but the comment indicated by that, and I think Sandra is going to help expand on it.
Is that a lot of *Salmonella* it starts at, especially the stereotypes of concern that are prevalent in human illnesses can be detected in the egg at the hatchery. And so, were the farmers are, if you'd want to say inheriting this *Salmonella* and then every step we do in the process therefore just tries to reduce what was there at birth.
So that's my limited understanding, but Sandra, did you have more details on that?

Eskin, Sandra - OSEC, DC 1:27:53
Just a little bit more. We do mention the program in the proposal in the preamble when we talk about other routes, at least initially, to try to deal with preharvest contamination and bring down the loads. We, that is to say FSIS, has engaged with APHIS, which is it again, it is a voluntary program, but widely used. Currently, it doesn't quite cover what we're looking at in this context, but I think there is a desire to continue to engage.
It has a very specific process.
How to change the standards in the programs and amend them, so I would encourage any stakeholders who are interested in this as a good option to address preharvest to talk to us at FSIS. Because it's an ongoing process and it could in fact help us again, reduce contamination. So, there's information about NPIP on the APHIS website.
It is an APHIS program.
It has a lot of history. It goes back to, I think maybe the 1930s, and of course, there are industry representatives on this call, I'm sure who know a lot more about it than I do, but I think it's a conversation that should continue. Thanks for bring.
It up Roseana.

Sarah Sorscher 1:29:19
And then I just had one more follow up for Rosanna which is, do any of your members currently produce ground beef, and how does the liability work for cases where that has *E. coli*, one of the STEC *E. coli*?

RB

Rosanna Bauman 1:29:34

Yeah. Thank you for asking that.
Actually, I also operate a USDA inspected red meat plant, so I'm both a producer and a processor and a fee-for-service processor of red meat.
That is one thing that is definitively different about this proposal. As opposed, so I already deal with adulterants in ground, in a product that I help produce for myself and for other people.
One defining difference between this proposal as an adulterant and the *E. coli* 0157H:7 as an adulterant is that one is
just in ground product, not in whole muscle for starters.
There's no explanation given why this is covering whole muscle.
Why it is in the entire chicken?
Clearly people undercook whole muscle, ground meat, whole muscle beef, way more frequently than they do poultry.
That's never been explained.
The *E. coli* in ground beef is, since it's I'll, I'll just say this as a small plant ground beef is dry, aged in my small plant.
Obviously, it's not in other ones. Dry aging after six days, any *E. coli* contamination in red meat generally comes from the exterior of the carcass. It's not endemic in the muscle, in the muscle meat.
So my prevention plans are to treat the outside of the carcass.
I let it dry age for six days.
That virtually kills the harbor, the harboring spot for the bacteria.
It makes it a very unlivable situation.
I've never had a hot test.
Most everything comes back at 0 when I do test my ground beef, but so there's the nature of the beef. We peel the hide off.
It's the skin underneath.
The skin dries out.
It's also treated with antimicrobial, in contrast to chicken.
Theoretically, I'm leaving the hide on.
I'll acknowledge that, the feathers come off the hide. The skin is left on most, and that's other than a gut spill, like on a beef, but once again, everything is on the

exterior of the bird.
The interior of the cavity, the exterior of the bird hide. So, there's no explanation for why boneless, skinless chicken breast, chicken tenders, anything without skin would be considered subject to an adulterant.
You could say, well, maybe cross-contamination. You'd be subject to the same cross-contamination risk in a red meat plant.
E. coli O157:H7, specifically is not endemic to beef the *E. coli* is, obviously O157:H7 is not.
So there's also that defining difference there.
I'm not dealing with something that's commonly found in ground beef.
That's my understanding.

SS

Sarah Sorscher 1:32:41

So.

RB

Rosanna Bauman 1:32:42

That's my understanding as a small plant producer.

SS

Sarah Sorscher 1:32:44

So, it sort of comes down to, it's very rare. If it did occur with the liability be on you to cover the costs in the same way you think, you project it would be for poultry or is that liability different for ground beef?

RB

Rosanna Bauman 1:32:57

So I have had to say condemn customers beef that have once I kill them and open them up and they're full of infection or something.
The rare cases that that's happened, the farmers been like, "yeah, I knew it was not doing very well" or "oh, that doesn't surprise me. She had a bad hip."
So I've not had to condemn for any of the other stuff. Of actual invisible thing that the farmer couldn't be aware of, which obviously *E. coli*, *Salmonella*, *campylobacter*. They're all invisible and I would imagine, should that scenario happen with beef.
That I would probably conceivably have to foot the bill for that as well because they would all say, "you know, that's fine. I could have just took it home and cooked it. You know it would. It's fine, it's fine."

Which is true.
Thorough cooking does kill *Salmonella*, and which is why I feel like the option to return to owner or product that is adulterated given a not for sale thing would be a nice solution for a small plants to have.
I feel like our risk is hundreds and thousands of times more of having the opportunity to condemn a customer's meat with this current proposal then what I'm currently dealing with in the red meat.

SS

Sarah Sorscher 1:34:34
Thank you.

RB

Rosanna Bauman 1:34:37
I appreciate, those are good questions.

Bailey, Shayla - FSIS 1:34:38
Yeah. Really appreciate the discussion.
Thank you for that.
So again it's still open if there's any other panelists or FSIS folks who have questions or would like to discuss what we've heard today.
I leave it open to you before I open it up to the our public attendees.
Hi, Matt.
I see your hand up. Please go ahead.

SM

Stasiewicz, Matt 1:35:06
Wanted to maybe just echo of the points that that Ashley made in her list of questions around the education needs piece.
As I think you could see, you know, a bit from her presentation and then mine as well, that is as we move forward and that there really are opportunities for that. And that isn't spelled out what the path is particularly for you know coming from an academic institution that also has, you know, an extension arm to it. Although I don't have that in my appointment.
Just thinking through what that pathway is to develop those educational materials and I recognize that might not be directly
in the framework, but making sure that FSIS is thinking through how that will come

through.
Um, is important because I think it's both.
You know, for the processors to develop and then also for the regulators to move forward as well.
So I just think that's it's a relevant piece to think about.

Bailey, Shayla - FSIS 1:35:56
Appreciate that. Thank you.
Alright, I am not seeing any additional hands from my panelists.
You guys can always jump in later with any questions.
I do have some items that came in via chat. So, I will cover those in just a moment, and I do see Greg's hand raised. So, if you hold on just a moment, Greg, I'm going to go ahead and give everybody instructions on how they can participate in the question and answers and make their comments as well.
So for folks on the phone, you would press star 5 and that will raise your hand for us and then I'll be able to work to get you unmuted.
And you will likely have to press star 6 to unmute.
So if you want to raise your hand from calling in on the phone, you can press star 5 again. For those of you who are using the teams app, you should see what looks like a little hand icon and it says raise under it and that should raise your hand for us, and then we will be able to see that and work to get you unmuted. So you can ask your question or make your comment and then also you can put things into the chat and I am happy to read them off or have your questions addressed, so that is another option.
And you should see a little chat bubble that you can click on to add your comments or questions to the chat.
So now, I know earlier in the in the call we did have a question come in from Zach. In the chat, and so I'm going to read that off. Zack says,
“We are a Canadian establishment. We export our poultry product to the USA. We have a shelf life of seven days.
How does this new rule impact our product since it will take some days before having the serotype results?”
And then we did have another. It looks like Gerard chimed in with a similar concern. With the same timeline for products that would be imported into the US. So, I

wanted to give a chance for FSIS folks to maybe provide some clarification there.
Rachel, hi.

EF

Edelstein, Rachel - FSIS 1:38:06

We did not actually propose, you know what the effective date would be for imported product, Um but, the we did.
I mean the imported the relevant product would be subject to sampling under the finished product standards should we have a final rule.
And at this point, and we did outline the time, some of the timelines like for what they are right now in our preamble. But we're expecting that if the rule goes forward, you know that those timelines should be shorter by that time.
We explain, we can get the enumeration results relatively quickly, but the serotyping takes longer at this at this point.
Thanks.

Bailey, Shayla - FSIS 1:38:57

Oh, hopefully that helps those folks, yes.
And so Greg, I see your hand up.
So you should be able to unmute and turn your camera on if you would like to ask your question or make your comment.

GG

Greg Gunthorp 1:39:12

I first I had a question.
Can I make a comment about what Sarah and Roseanne were talking about and still have a chance to ask my other question later?

Bailey, Shayla - FSIS 1:39:20

Absolutely. Please go ahead.

GG

Greg Gunthorp 1:39:21

OK. And perhaps it even is addressed to Matt or some of the FSIS people, but I was wondering if someone would comment on the prevalence of *E. coli* 0157.
I mean, in my rough numbers off top of my head, is I believe that it's about one in

1000 tests on *E. coli*0157.
Where you're looking at 2 to 15% depending on the class of poultry for any positive *Salmonella*.
Excuse me, *Salmonella* serotype.
So I think the risk of those two, and you know and they're completely different beasts. And I think also, if Matt would comment a little bit, I think on process control. My understanding on *E. coli*0157, if you have very good process control you have almost no likelihood of 0157. Where his data today clearly demonstrated that you can have good process control on poultry slaughter and still have the occasional. *Salmonella* sample that is going to fail this new standard.

Bailey, Shayla - FSIS 1:40:27
Thank you, Craig.
So Matt, did you want to come back and maybe share some insight on that?

SM

Stasiewicz, Matt 1:40:33
Well, I mean it's a very quick response and that all the information that I was presenting was about *Salmonella* in raw poultry, right?

SM

Stasiewicz, Matt 1:40:42
So I don't have any specific comment on *E. coli* 0157:H7 and don't wanna talk beyond what I know so.
Yep.

Bailey, Shayla - FSIS 1:40:51
OK.
I appreciate that.
So I don't know if there's anybody else on the panel who wanted to maybe try and address that and if not, that's OK and we can go back to Greg to see if he has another question.
So that may be something we have to look into comparatively, Greg, but appreciate you bringing up that point.
And then you said you might have another question.

GG

Greg Gunthorp 1:41:19

Yes, I for sure have another question and I apologize ahead of time cause, I jotted it down so that I think just like everyone else my life has been a little too crazy lately but I wanted to make sure that I got my points.

I had a question and this is primarily addressed and it's actually similar to Roseanne's, but slightly different. And my question is on the, this Federal Register notice in the statutory requirements. That agencies have to ensure that these Federal Register notices adequately address the costs and issues to small and very small players in the industry.

On our farm, I'm an artisanal producer and processor.

We own a very small USDA inspected red meat and poultry establishment.

Ah, but my questions would be several and I would ask anybody if they want to see my complete written comments.

I'm gonna submit them to the portal after, but I have a Facebook group me and my daughter runs called Politics From the Pasture.

My this is on here, I welcome anybody, industry or whatever to comment on these, but um.

My first question, if you adequately address, do little producers have any control over the serotypes of *Salmonella* coming onto their farms?

This was touched on earlier, but *Salmonella* is largely transmitted horizontally from the breeder flocks to the hatcheries and onto the farm.

And with the consolidation in the industry, I'm not sure that producers have the opportunity if they determine with the root cause analysis that the hatchery or the breeder flock is their source of *Salmonella*.

In lots of cases, they don't even have an option to switch to something else.

So I don't think they have a legitimate choice on their chick source. In the same vein, do these very small establishments have legitimate choices in a concentrated industry?

To pursue establishments that will co-pack fully cooked, ready-to-eat chicken in the event of an unfavorable test?

Another question is, has USDA FSIS done the monitoring and validation to ensure the variability and temperature in shipments? If we're going to switch to enumerated sample rather than qualitative 0 tolerance sample, are we making sure that the

variability? A lot of these very small establishments are remote, establishments without full time veterinarians.
No 2nd shift.
Shipping from FedEx Express is probably significantly longer for those establishments to get to the lab than it is from the largest establishments.
And just wanted to make sure that the temperature of the product or the temperature of that testing is not impacting any enumeration.
Um, and then a question on frequency and I think this one I would have added when Sarah asked that question.
I think this ultimately comes down to, from the little plants. I think a lot of them feel that this is not fair.
You know, if there's approximately 8.7 billion chickens raised in the United States and the USDA does approximately 8,000 *Salmonella* test, that's approximately 1 test for every 100,000 birds.
And, you know, Roseanne touched on that. In our plant when we were still doing chickens, we were getting tested at approximately
one for every 4000 birds. A frequency of about 250 times higher. When USDA is just evaluating process control with that testing, with a non-destructive test, it's no big deal. When there's product that is exposed to the potential for a recall and you're testing it
250 times higher that starts to become a significant cost disadvantage to little plants.
And I don't feel that that was addressed properly in the Federal Register notices, as one of the costs or issues for little plants.
And in the same vein.
On lot size, I'm not sure that lot size is addressed adequately in the Federal Register notice.
You know, I think that.
I'd really love to know what representative lot sizes compared to the quantity produced in establishments in across the various sectors of size, but you know. For plants running 135 to 175 birds per minute on two lines, two shifts a day. How many birds does that test represent?
And if you got a plant that's doing two to six birds a minute running for one shift, how many does that test in that plant represent per day?
And which one of those is more of an impact on the cost and risk to their business and um?

One other question that I've asked before, and I'm not sure that I have access to the data. And that is the, through the past history of the *Salmonella* Performance Standards, I would like to be able to access the information on rising into category three. That's impact on FSAs, enforcement actions, and resulting inspection or resulting suspensions and the time of those suspensions based on size categories. The we have evaluated that information in the past on humane slaughter violations, and it and it at face value, very much appeared like that it was little plants were being held to a different standard in that. And I just, you know, little plants oftentimes have the difficulty of having the time and the resources. And I just was my questions were just basically on, you know, as this rule making process goes forward if we've adequately addressed the true cost and risks and issues to little plants.

Bailey, Shayla - FSIS 1:47:47

Thank you.

I see you came online, Sandy.

So did you wanna talk about this a bit?

Eskin, Sandra - OSEC, DC 1:47:51

Yeah. I just wanted to, yeah, definitely.

Unless there's someone else from the FSIS bench who wants to address any of the specific questions that Greg just posed. I think your questions covered all three components, Greg. All important questions, all questions that the agency needs to think about, and of all the questions that keep doing this. But it's the reality you need to share with us information that you believe would be helpful for us to craft policies and approaches that would work for your, you know, your community.

And again, we can continue this conversation offline.

I encourage you to set up meetings and kind of go over some of the issues that you raise and obviously to include them in a written comment.

I know that's a lot of work you have to run a business so you can use all of these outlets, but they're all important questions.

Which I think we need to think about.

And again, I encourage you to share and reach out to FSIS so we can start dealing with them, you know, reasonably soon there's a lot of stuff we need to go through. To get this to final policy. Thanks Shayla.

Bailey, Shayla - FSIS 1:49:13

Appreciate that, Greg and thank you for raising all those questions and sharing your perspectives with us.

So Pat, I also see your hand up.

I'm gonna go ahead.

You should be able to unmute and turn on your camera if you would like to and happy to hear your questions or comments. You may have to unmute on your end, too.

I don't see you unmuted yet.

You will need to unmute within Teams.

OK, Pat, it looks like we may be having some technical difficulties.

We will come back to you.

So, I'm gonna leave your hand raised, and if you can get unmuted on your end, your everything is enabled on my side.

So, you should be able to just unmute and talk, but I will come back to you in just a bit. Angie, I see your hand up as well and you should be able to unmute and turn on your camera if you wish to make your comment or ask your question.

Angie Siemens 1:50:26

Yeah, thank you. I do.

I do have a question.

A point and then I'm curious if someone in FSIS has considered this. One of the things that concern me about this particular proposal on SPC is that, I'm not. I believe there should be some process control dynamics built into the regulations that would be able to have an establishment, you know, establish what those process controls are that fits their facility and um.

Then they can verify it that it actually is matching their finished product in the mix. FSIS has, over time, put in some pretty narrow standards in the regulation. Right requirements, where they're very specific and come to find out that in a few years that they were not applicable, or some other innovation came in place that they're no longer useful.

In the mix and so I am concerned on two fronts with this particular proposal being as detailed as it is. Is one, they do offer a little couple sentences that says if you have an

alternative, you can submit it to the agency and be able to do an alternative to what has been suggested. But Rachel earlier made a comment, Edelstein, made a comment that the agency wants to take this data and use it as, to do trending analysis over time. Which means that you got to have the same type of data. So, I am not encouraged with that statement to say that I can innovate, potentially find a better metric that actually monitors my process and get that approved by the agency.
So, I have concerns on that. The second is, what if we do find out that long-term this metric, which the agencies already made comments that APC isn't necessarily related in all cases to the finished product, but that metric is no longer applicable towards moving forward, and now we've got it into regulatory language.
It doesn't offer the ability, as I've heard the agency talk on several occasions, is to have flexibility in the regulation to be able to move as we learn more. This one seems contrary to that.
So I guess there's a couple things in that. One, it doesn't appear the agency is really welcoming innovation to look at an alternative.
And two, I really struggle with the long-term application of this and being able to be flexible and move forward in the way that the regulatory proposed language is written. I think there's other ways of being more flexible with the language that would fit a longer term perspective in and an innovation standard on that.
So it's a couple comments.
I just wondered if policy has some comments on that or is there some discussion of not being as detailed in the regulatory language as an alternative to what's in there today?

EF

Edelstein, Rachel - FSIS 1:53:55

Angie, I just, I this is Rachel. Just to follow up.
So we're just.
I mean, we were, we already have the we're just updating the current process control requirements.
So you know, just to try to clarify and standardize. So, did you,
do you have concern with the way that, like with the current requirements?

AS

Angie Siemens 1:54:26

Yeah, cause, I don't know how useful they are.
So one, I'm not totally sure that they're, they're as useful as.

Edelstein, Rachel - FSIS 1:54:28
OK.

Angie Siemens 1:54:33
In the Turkey space.
My data that comes off the slaughter line is not at all related to my ground Turkey. So, we'll be doing it to provide you data, but it will not tell us that we've made improvements or have an issue or potential issue with our ground Turkey. And you saw a little bit of that data that was presented in earlier presentations. So, we're gonna take a look at if I'm gonna spend money, right and time to do a metric, I want a metric that tells me something. What you have offered right up here is not one that would be useful to us in the mix. The second part of this is just you do mandate. I mean the way it's written is you, you're going to put in a micro monitoring very specific into the language. Unless you adjust that language, but the way the proposal reads.
It's very specific and once it's once it's written that specific in the mix, it's so hard to change, right?
We don't get regulatory change very quickly. So is there a way in bring in the language up a level to state "thou shalt have an SPC program," but without all of the detail. Very specific details in the regulatory language, which would allow everyone to make adjustments if we find other measures or metrics that actually have a better value than what this one seems to have in some of the data we've seen so far.

Edelstein, Rachel - FSIS 1:56:05
It would be helpful to know, I mean, I know in the preamble we talked about, you know that if establishments use our guidance that would, you know we would accept that, but the codified isn't that prescriptive. It would be helpful to know where in the codified your concerns are?

Angie Siemens 1:56:27
OK, we can put comments into that effect on there, right?

EF

Edelstein, Rachel - FSIS 1:56:29

That would be great. Thanks.

AS

Angie Siemens 1:56:34

Could you also address though, if I wanna do an alternative, which means my data wouldn't match to be able to do a national.

What the thought process is there of I mean, would we be able to? Let me back up. Our pre our current history tells us that is very difficult to get an alternative approved. So, we've not tried, even though we believe that we have a better metric than the current measure.

I don't expect, um, I would hope that that would shift moving forward, but I don't have great expectations. That if you are planning on using this data to do national trends, our ability to do alternatives, I think for me seems limited. And so is there, I don't know where the thought process on that and how you want to use that data nationally versus trying to find data that truly helps us at the plant level.

EF

Edelstein, Rachel - FSIS 1:57:37

Yeah. I mean, I think ideally, we wanted to have something where we would have some indication of you know what's going on at headquarters.

But I don't, I admit I don't think we worked out exactly how that would work. Cause you're right.

I mean, we have had discussions about that, like if people aren't using exactly the same, I mean not just the, not just the indicator organisms, but like testing could be different too, right?

I mean, we've talked about that.

So I think that's a that's an issue we're still considering.

AS

Angie Siemens 1:58:09

Thank you.

Bailey, Shayla - FSIS 1:58:14

Thank you for that.

Appreciate the question and the discussion.
So, Lindy, I see your hand up as well.
You should be able to unmute and turn on your camera if you would like and ask your question.
Make your comment.

LC

Lindy Chiaia 1:58:31
Thanks, Shayla.
This is Lindy with the National Turkey Federation.
Appreciate the opportunity to provide some feedback.
One of the key points I did want to make was related to flexibility.
Pretty similar to some comments that Angie made, so I won't belabor too hard on that.
I was encouraged by Doctor Catlin's presentation that the agency is open to alternatives and just look forward to learning more about what will be required in that review process for alternatives, should an establishment feel they have one that better fits their process.
I did also want to make a few comments related to component one.
Of the proposal, we're very much in support of the stance that was taken on component one and but do feel that there are continued opportunities to learn more on pre-harvest interventions. Um and one of those interventions that there's a lot of interest in is expanded vaccine options for the industry. And one thing I would really like to encourage the agency to do is to continue having conversations with USDA's Center for Veterinary Biologics on their process for approving vaccines.
I think that would be very critical to allowing for expanded opportunities for the industry and that's one that I think would be just really beneficial overall to furthering the food safety of poultry.
So, appreciate the opportunity to provide that comment.

Bailey, Shayla - FSIS 2:00:14
Thank you, Lindy.
All right. We did have some questions and comments come into the chat. So, I'm gonna revisit those. Again, folks on the phone.
You can raise your hand by pressing star five.

And then I will work to get you unmuted. And then anybody else using the Team's app, you should be able to raise your hand if you want to give a verbal comment or ask a question.
Pat, I do see your hand up again.
I will see if we can give it a try.
And you should be able to unmute on your end now.
We'll give it another, another attempt here.
You look to be like you're not unmuted, but you are enabled on my end to be able to unmute, yeah.

Eskin, Sandra - OSEC, DC 2:01:09
Um Shayla.
Excuse me, Shalya, it's Sandy.
I'm responding to Pat's comment in the chat here, and I'll definitely continue discussing that with her offline.

Bailey, Shayla - FSIS 2:01:13
Sure.
OK.
Great, yes, and I did see that she added to the chat some comments about consumer education and the need for labelling, effective labelling, labelling of raw products.
So, we do appreciate those comments in the chat and we'll see if we can connect with you offline.
So, I wanted to go back a bit in the chat and I did see that Michael Hansen asked regarding the hatchery and APHIS was the reference to NVAP.
So I didn't know if somebody could clarify that for him.

Eskin, Sandra - OSEC, DC 2:02:00
I'm sorry. What did he say?
Could you repeat that?
Does it?

Bailey, Shayla - FSIS 2:02:03
Sure. So, he was focused on the hatcheries and APHIS and was that a reference to

NVAP?
That's a different acronym, I think, than we heard mention before.

Eskin, Sandra - OSEC, DC 2:02:12
Right. That was my question. If you're there, Michael?

Bailey, Shayla - FSIS 2:02:20
I think he's asking which program you were talking about?

Eskin, Sandra - OSEC, DC 2:02:22
Right. The issue is right now it's not clear if the existing program could incorporate what we are focused on here in terms of human illness and *Salmonella* or if there needed to be another program.
I will follow up with him offline and talk about what what's what we've done so far and what the path forward.

Bailey, Shayla - FSIS 2:02:41
OK.

Eskin, Sandra - OSEC, DC 2:02:49
Thanks Ashley.

Bailey, Shayla - FSIS 2:02:50
Yes. And I think Ashley just chimed in and said it was NPIP, right and not NVIP, yes.

Eskin, Sandra - OSEC, DC 2:02:50
She did respond.
Yeah, I'm not sure what NVIP.
Thanks.

Bailey, Shayla - FSIS 2:03:00
Yes, appreciate that.
OK.

Sarah did make a comment when there was the discussion about 0157:H7 that we are looking at data now that is after decades of having an enforceable standard in place.
And so I thank you for that comment, Sarah, on that discussion, which happened a bit a bit ago. And then Michelle says, "The reported case of *Salmonella* appears to be based on epidemiological data compiled from all cases reported to the CDC.
I monitor CDC reports and the majority do not indicate poultry as the root cause.
Can you provide detailed CDC data on mortality and morbidity numbers directly attributed to poultry entering the U.S. food supply chain?" And Sandra, I see you came back on camera.
We did provide an answer in chat.
Did you want to add to that? Yeah.

Eskin, Sandra - OSEC, DC 2:03:49
Exactly. Yeah, I just wanted to say if Joanna wanted to add to it. She referenced its different documents and information and she gave a link to the IFSAC report, which does food source attribution.

Bailey, Shayla - FSIS 2:03:56
Yes.

Eskin, Sandra - OSEC, DC 2:04:03
So again, Joanna, if there's anything else you wanna add to what you put into the chat.

ZF

Zablotsky-Kufel, Joanna - FSIS 2:04:10
Sure. So, I mean the perhaps one of the important points is, right, that I think the person is referring to the MMWR, which CBC puts out annually with the Food Net data. That's sporadic illness data and, unfortunately, we're not able to specifically attribute those sporadic illnesses for *Salmonella* or any of the other pathogens to specific food products.
So, we have to use other data sources.
And so, specifically, we use the CDC outbreak data or NORS. Both CDC Food Net and CDC NORS data is available online.

And then you know, thirdly, as you said, we use the IFSAC data, the attribution data.
So we take the outbreak data from CDC and we parse out.
Where the outbreaks are coming?
What foods are attributed to those outbreaks?
And so those are kind of the three major data sources that we use to determine which cases are *Salmonella* in poultry or how many cases of *Salmonella* in poultry there are.

Bailey, Shayla - FSIS 2:05:16
All right.
Thank you, Joanne.
I appreciate that additional information, and you did add links in the chat, so appreciate that, too. So, folks want to go take a deeper dive into that. You can certainly find that information in the chat.
OK.
Let's see.
So Keith says "Since plants that only further process will be subject to the finished product standard.
What are process control expectations when we know that parting at carcass can expose internal *Salmonella* sources? Parts as finished products may pass testing at slaughter plants, but that microecology may change after running down the road for several hours in a combo and then being processed further."

Edelstein, Rachel - FSIS 2:06:03
Hi, Shayla I can start.
I mean, this is something that we are dealing with right now. Because we have *Salmonella* performance standards for at carcass, you know slaughter establishments that are producing carcasses and then we have the parts standards and we have the comminuted product standards.
So, the I mean, the general expectation is that further processes processors are addressing that hazard as best they can to reduce *Salmonella* to acceptable levels.
Thanks.

Bailey, Shayla - FSIS 2:06:47

Thank you, Rachel.
Appreciate that, all right.
And then just scrolling back.
I didn't want to miss this one. Samantha says, “What is the pathway and timeline for us small plans to even enter that conversation other than just voicing concerns here like Greg did? Greg very well spoken. It is hard for us to even take the time to pause production and sit in on this webinar.” And I believe,
Sandy, you did respond to her and said that you know that you understand.
And you think it should start with a meeting with the FSIS point people working on this proposal to discuss the issues raised by Greg. And it can even be done virtually, and we have until January 17th really to submit those written comments.
So that's a good reminder that folks can continue to weigh in. Appreciate that.
OK.
Let's see.
Also in the chat.
Let's see.
Greg asked if NPIP only tests for Pullorum and Typhoid?
I'm not sure if we have somebody who can answer that, about that AHPIS program, but I think that may be part of the question that you were alluding to. Right, Sandy?
That the program needs to be looked at further to see if it meets the needs.

Ashley Peterson 2:08:10
Shayla, hello, this is Ashley.
I put the response to Greg in the chat as well.

Bailey, Shayla - FSIS 2:08:14
Oh! did you, I see that, OK.

Eskin, Sandra - OSEC, DC 2:08:16
Right there.

Bailey, Shayla - FSIS 2:08:17

Thank you, Ashley.
Yes, with a great link. Thank you.

Eskin, Sandra - OSEC, DC 2:08:20
And again, we started looking at it.
We've reached out.
We've participated in the most recent NPIP biannual meeting, and we'll continue to try to engage to see if we can leverage this program again to help bring down pre-harvest contamination levels with the *Salmonella* that makes people sick.

Bailey, Shayla - FSIS 2:08:43
Thank you.
Appreciate that concerted effort to answer Greg's question.
All right. Pat weighed in and said "Thank you, but my concern is not only about the labeling. I think this group needs to understand that there have been multiple efforts for large scale education like the Ad Council, but it does not have much effect. I believe the main reason is a lack of state or local educational support like what is provided by extension. We need more congressional support for these programs, but they have been seriously underfunded for many years.
Unfortunately, I don't see that changing in the near future.
So we need to look at what can be done to improve labelling and to improve process control. This rule very much needs to be completed.
Thank you everyone for great presentations."

Eskin, Sandra - OSEC, DC 2:09:31
And I'm happy just to respond just a little bit obviously going forward.

Bailey, Shayla - FSIS 2:09:34
Sure.

Eskin, Sandra - OSEC, DC 2:09:39
Funding for all federal grants is clearly under the microscope, and I think it's highly unlikely that Congress would support additional funding.

Therefore, we have to be perhaps a little creative or use existing programs.
Pat, I know you've been involved for years with the Partnership for Food Safety Education, and that is clearly one.
One approach you know working with them, working with industry again in my comments we are taking a look at safe handling instruction label.
Label is not the education program, but it's an important thing that we can do within our authority, in the system resources. So on that, just stay tuned.
And again, we gotta be creative, I think about education programs, including again, we've heard this and it's an important point.
Home EC is not part of the sort of general, certainly public school curriculum, and that's a place where a lot of important things.
We learned by all of us.
I'm done Shayla.

Bailey, Shayla - FSIS 2:10:53
Alright, thank you.
No, I appreciate you chiming in with that.
I think that's all very important.
Bill, I see your hand up and you should be able to unmute and turn on your camera if you wish.
You'll need to unmute on your side.

BP

Bill Potter 2:11:22
Thank you very much.
I assume you can hear me now.

Bailey, Shayla - FSIS 2:11:25
Yes.

BP

Bill Potter 2:11:27
Two very good discussion meetings, both the previous one a couple days ago and today. By introduction, I'm Bill Potter. After a long industry career, recently have got into the poultry processing and food safety extension world with the University of Arkansas. And then discussing kind of where we're at with some of my colleagues in

academia, as well as around a number of poultry companies.
I've been kinda asked to give three main messages that we need to have as continued help in this whole realm of the new proposal.
I think everyone is OK with something around SPC. We all agree SPC works.
It's something that we do already and most of our operations, some very extensively, some more in a basic format.
The dilemma we have is we don't want SPC to be restricted.
There are many SPC tools available.
Very many ways to use SPC to get, to glean a lot of good data, and I agree with the points that were made by Matt and Ashley and Angie and others around having the opportunity to be flexible.
You know, a good example would be, if I'm a poultry slaughter plant and my incoming rehang load is continuing to
decline. That may in fact be such that the delta difference between my rehang and my point of pack sampling actually becomes less. Although the finished product is safer.
So that's a good example of why we need some flexibility.
It may be that in some plants, particularly have very low rehang numbers, that it may make more sense in those operations to have something else. Maybe just a stand-alone, baseline level that's identified.
Use classic SPC rules for upward and downward trends and outliers and take action accordingly.
So anyway, flexibility is the first thing that I'm hearing around the industry that we need.
I agree with that statement that's already been made today.
The second one, and I really appreciate you hearing about this. This was a request that I've heard in doing some SPC training this week.
That others have been asking about. But the second thing is, this idea of dissociating corrective actions. As we typically think of them in 417 corrective actions, as we think of them in industry and HACCP are something that you do when a critical limit is exceeded.
This is, I think, what I'm hearing today, not what we're talking about when we're talking about corrective actions, when looking back at your data set in your microbial monitoring plan.
So clarifying around that would be most helpful.

Going forward, it's two different things.
So we're not talking about holding product, I don't believe after the comments I heard today.
Rather, maybe looking back at process control, maybe looking at your process capability index and responding accordingly.
So, that's the second big thing that I wanted to communicate. And then the third one is kind of going back to the call we had a couple of days ago. And this is around the whole worry that the industry has, we all have around the microbial lot separation.
We're all working on what does that look like?
Can we, you know, can we come up with a reasonable, manageable way to do that?
If we can't, we're going to be talking about a tremendous amount of product, retained, held and in a state that we can't deal with, as Doctor Peterson had mentioned.
So if FSIS has some further thoughts around microbial lot separation, I believe there may have been or are currently in process some guidance documents coming out in that regard.
That's the one that's got us all kind of trying to find the solution.
So, those are my comments, but again thank you for the open dialogue and appreciate the opportunity to share those.

Bailey, Shayla - FSIS 2:15:52
Thank you, Bill.
We appreciate you sharing your thoughts and perspectives as well.

BP

Bill Potter 2:15:56
Sure.

Bailey, Shayla - FSIS 2:16:07
All right, so revisiting the chat. I do see that
Betty Jo had a comment and said "I understand most of the framework that has been done has been around slaughter facilities. However, for the further processing facilities, we would like a little more guidance." And I see that Sandra acknowledged that in the chat.
And then let's see, Pat says, "I agree. We need to have more in classroom food safety

education. But school boards across the country have decided that school curriculums need to spend more time on math and reading, given the upward trend of lower test scores, than on something that parents can teach us at home. As a former teacher, I don't know how to resolve that issue across the country. It is very frustrating, but on food safety education, we really need more federal programs to help educate our large populations."
So again, thank you, Pat, for your comments and thoughts on that.
All right. I do not see any additional hands raised and I'm not seeing anything more coming into the chat.
I'll do one last call to see if there are any questions or comments or things folks would like to discuss.
So again, you can raise your hand. Folks on the phone can raise their hand by pressing star five and that will raise your hand for us in the in the Team's system.
Others, you can use the raise your hand icon or put something into the chat.
Then I'm going to give it just a little bit for folks to find those options.
And see if there's anyone else who has a question or comment.
Alright, I am not seeing anymore.
Looks like some folks are exchanging some information so they can, maybe meet up or have some further discussion offline.
I love to see that, that this dialogue has spurred those connections.
So I'm going to go ahead and hand it back over to you, Sandra, for some closing remarks.

Eskin, Sandra - OSEC, DC 2:18:18
Thanks very much. For Shayla, thank you once again for excellent moderating. And I also wanna give a shout out to Julie Lastra and Colin Finan here, who helped coordinate these public meetings.
And I will just close on a broken record, but it's important, January 17th is the deadline for filing written comments.
So please, I know it's a challenging time of the year with the holidays.
But it's so important that the agency has a very robust record going forward as they figure out what the best approach is to bring down illnesses, *Salmonella* infections linked to raw poultry.
Thanks again.

Very valuable discussions. Very interesting. And again, it sounds like they'll be continued among the community here.
Enjoy the rest of your day and thanks once again.

Bailey, Shayla - FSIS 2:19:25
Thank you, everyone. This concludes our meeting.

Bailey, Shayla - FSIS stopped transcription