

**FSIS Salmonella Categorization Process for Raw Chicken Parts and Comminuted Poultry Webinar:
June 13, 2018, 1-3 p.m. ET**

[START OF TRANSCRIPT]

Aasif, ATT: Welcome and thank you for joining today's Posting Data for Raw Poultry and Comminuted Poultry Products. Please note that all participant lines will be muted until the Q&A portion of the call and we will provide you with instructions on how to ask a verbal question at that time. However, you are welcome to submit written questions throughout this presentation. This also will be addressed during the Q&A. To submit a written question, please use the chat panel on the lower right-hand side of your screen and then choose All Panelists from the send-to dropdown menu.

If at any time you require technical assistance, please send a note to the event producer or call our help desk at 888-796-6118. With that, I'd like to turn the call over to Selena Kremer.

Selena Kremer: Thank you and good afternoon. Thanks to you all for dialing in to today's webinar on FSIS *Salmonella* Categorization Process for Raw Chicken Parts and Comminuted Poultry Products. This webinar is being recorded and will be made available on the FSIS website. Let's get started with the webinar. It's my pleasure to introduce to you Todd Reed, Chief Operating Officer.

Todd Reed: Hello, everyone and thanks for joining us today. We will take questions at any time but we're going to do some natural breaks between sections. That might be a good place for you to make sure you get your questions in and be prepared for that.

Today, as you know, we're going to talk about *Salmonella* categories in raw chicken parts and comminuted poultry products and really the agency's path forward and where we're going with that. This talk is going to have four main points: one, how samples are assigned; secondly, how then we take the results of those samples and determine categories. We're going to give some real-life examples of how establishments move between categories, and then we're going to talk to you about when and where the data are available, so you can look at that information.

Moving forward to the FSIS sampling procedures. We're going to talk about a couple different parts of sampling, which I hope we will clarify this to anyone who doesn't have the details. We want to look at how we schedule routine samples, the frequency of sampling assignments, which I know we get a lot of questions on, and we want to look at scheduling a follow-up sample as well.

Scheduling routine samples – what we're really talking about in today's presentation are establishments with an average daily production volume of greater than a 1,000 pounds. We do sample establishments that do less than that, but we do that under another sampling project that doesn't categorize, and

I'm not really talking about that today. We're talking about those products that are sampled. We are talking about specifically raw chicken parts, comminuted chicken and comminuted turkey. Throughout this presentation, if I say frequency, I'm referring to the number of samples assigned each month to an establishment just to make sure we're using the terms consistently.

All right, moving on to slide six then, sampling frequency. For every establishment that makes an eligible product, what we do is we go to the database and we find those products in the PHIS profile and we pull up the list of the establishments, we pull up the products, we pull up what the volume is and how many days it's produced for a month. That information is put in an algorithm, and it basically takes all the establishments that produce product that are eligible and how much they produce, and it allocates all the sampling resources at FSIS that we have. That ends up being anywhere from zero to five samples that are more or less distributed based on volume but just so everyone understands it's done statistically, which means it's not an exact number. One month it could be three or one month it could be four depending on where an establishment happens to fall on that cut point. There is some variance because it is statistics on nature. It's not deterministic.

We also look at the history of *Salmonella* positive results and again, we're looking at specific product's category so we do this separately for raw chicken parts, raw comminuted chicken and raw comminuted turkey. We really do it internally in the week. It's like three different things but for you, it probably shows up and you would think of it the same but it's really three separate things for us.

Our goal, if resources are available, it's to try to get to roughly 52 samples per year in the largest establishments. We really would like to get to at least 10 samples per year for everyone else that makes eligible products and kind of foreshadowing by getting to 10, that statistically allows us to categorize establishments with pretty good confidence that we have into the right place. As you'll see, we even adjust for that just to make sure in case there's any error for an establishment with less so we don't end up in a bad spot. We'll talk about that in a couple of minutes. All right. That's what I want to talk about. That was routine sampling.

The follow-up sampling, and this just started not that long ago. In April of 2018, FSIS designed follow-up sampling sets to all establishments with products exceeding the performance standard. Then, almost everyone got 16 samples but we really do have rules on how it's designed with, here on this slide. Basically, if an establishment produces four or more days per month, they get 16 follow-up samples and if they only produced three days a month, the less they would get, eight follow-up samples. Again, almost everyone got 16 but there is a provision where establishments that really have a low production volume, they wouldn't even be able to get through 16 in a year so that doesn't make a lot of sense.

When the follow-up samples are assigned, really, we want these samples to be collected approximately 30 days after that establishment is category three or when they got that category three alert. Realize since we just started it in April 2018, there were establishments that might have hit category three well before April 2018 and we assigned those alerts and no samples started in. Really, we had a big wave that would start in April but going forward, category three to that establishment and then the samples would be assigned approximately 30 days after that.

In contrast to the routine samples, then I guess I forgot to mention this on the routine sample part, if an establishment gets say four or five routine samples, really, the inspector is going to collect them randomly across the month but more or less, it would be like one a week for example or if there were two every other week, but again it's random. It doesn't have to be the same. For routine samples, we really want them to do as quick as possible so it could be up to one sample per shift.

Selena Kremer: For follow-up.

Todd Reed: For follow-up, for follow-up samples. The last four there on this slide is we're only going to do one sample per shift. If we did a follow-up sample or routine, we're not going to do the other one as well as at the same shift. It's only one sample per shift. All right. Let's pause right there and see if we have any questions.

Selena Kremer: Aasif, ATT, I do see we have one question from a participant asking if the slides will be available for download. Yes, they will be made available on FSIS' website after the webinar. Are there any other questions, Aasif, ATT?

Aasif, ATT: At this time, we have no other questions.

Selena Kremer: Okay. Can you go through the instructions for the phone?

Aasif, ATT: Absolutely. If you would like to ask a question over the phone, please press #2 on your telephone keypad. You will hear a notification when your line is unmuted and at that time, please then state your name and question. Once again, if you would like to ask a question over the phone, please press #2 on your telephone keypad. While we wait, Selena, it looks like we did receive another written question.

Selena Kremer: Yes. The question is, "Is the algorithm that determines the sample number publicly available?"

Aasif, ATT: Pardon me for interrupting, Selena, you may have muted your own device, as we are not able to hear you.

Todd Reed: Yes, one second. This is Todd. There's no reason it's not available. Honestly, I don't know that we've been asked. It's really just like a random selection. There's

not a lot, but we can look into seeing if there's a way we could make it available. It's just I'm not really sure what the random choice is.

Aasif, ATT: We have received a question over the telephone line. That caller line has been unmuted.

Tim B: That was me who asked the typed-in question, so you can ignore this. Thank you.

Aasif, ATT: We do have another caller in the queue. Next caller's line has been unmuted.

Angie Siemens: Hi. This is Angie Siemens, I got a question relative to the intensified sampling. If you end up in the category three and you were sampled in April, how quickly might you come back and do another sampling in case you stay in category three or it takes a while to get out of category three? When would another intensified sampling takes place?

Todd Reed: At this time, the agency only does one follow-up set for an establishment in the category three. Yes. The only difference would be if an establishment came out of category three and then went back into category three, then it would qualify again for another follow-up set of samples. But if it's in category three, at this time, we just do one set and that's it.

Selena Kremer: Todd, we have another question, "What is the purpose of waiting 30 days to collect follow-up samples?"

Stevie Hretz: That is outlined in Notice 18-18. That was to give the establishment an opportunity to do their root cause analysis and make any changes to their HACCP system any corrective and preventive action through validation, reassessment that's needed before we start the follow-up sampling, which should inform as whether those actions were successful.

Selena Kremer: Thank you. We have another question, "Are follow-up samples identified or labeled differently on the LIMS results report from the regular samples?"

Todd Reed: The answer to that is yes. Every sample that FSIS takes has a project code. When you log in to LIMS, it would actually tell you the project code that it will go with it.

Stevie Hretz: All of the follow-up samples for all the different categories start with an F.

Selena Kremer: Thank you. Another question, "If the follow-up sample is taken on a particular shift and a routine sample is also taken, will both sample results stand?"

Todd Reed: Normally, we would never collect two samples on the same shift. It would only be one sample per shift. That shouldn't happen that this is an issue.

Selena Kremer: Okay. Thank you. I do not have any other written questions. We can go ahead and move on to the next section. Here we got one. "If the plant produces no eligible parts for testing such as front and leg quarters only, what counts towards the parts category?"

Rachel Edelstein: I think it wouldn't be subject, they wouldn't be subject for the performance standard. That's just our—

Stevie Hretz: Yes. There is a program sampling quarters and halves and that is currently exploratory and not under the performance standard. Someone that doesn't have any eligible parts wouldn't be subject to the parts performance standard. That would not be categorized.

Selena Kremer: Thank you. Another question, "If a follow-up sample is taken on a particular shift and a routine sample is also taken during the 16 sample window sets, will both sample results stand?"

Todd Reed: Yes, all the results would stand. The point is we would only take one per shift. If they took a routine sample on shift one and a follow-up sample on shift two, it's still one sample per shift and they would all be valid results. We just take one sample per shift.

Selena Kremer: Okay. Great. Thank you. Aasif, ATT, as long as we have no other folks on the line, we'll go ahead and move to the next section.

Aasif, ATT: At this time, we have no other questions on the line.

Selena Kremer: Okay. Todd, one more question, "If the plant produces only one eligible part such as a wing, will only those samples be counted toward parts?"

Todd Reed: The answer is yes. We have to choose from the eligible products and if there's only one eligible product, then it would get chosen every time.

Selena Kremer: Great. Thank you.

Todd Reed: All right. What we'll do is we'll go ahead and move forward to make sure we finish but at the end, if we have more time, feel free to ask more questions on this topic as well.

Next, we want to talk about how FSIS determines an establishment's category. Really, from my perspective, I like to think about how we do establishment categories is a two-step process, and we'll get into that on the next slide. Before we do that, let's define what we mean by categories. We'll define what we mean by categories on slide 10. FSIS has three categories where category one is Consistent Process Control. The important part is that it's 50% or less of the maximum allowable percent positive. Category two is Variable Process Control. It's where you're greater than 50% of the maximum allowable but you're below that threshold. You have less than the maximum allowable. Category three is where you have greater than the maximum allowable. Not on the slides, sometimes if an establishment did not have enough samples, it wouldn't be categorized and then it shows up as an N/A. These are the three categories.

Okay. Then, going to slide 11, we'll talk about the two-step process. For me, that is easiest to wrap my head around it is, step one happens every single week.

Every single week, we look at the last 52 weeks of samples that that establishment had, and we look at all eligible samples in those 52 weeks. For all those eligible samples, we said, "If we were only looking at that one week," which we're not because step two still happens, all right, that's the key step. Step one, just looking at those 52 weeks, where did that establishment stand compare to the performance standard? That's step one. For that one week, we say what is the score of that one week?

Then, step two, then we look at the most recent 13 weeks of step one. We take all your step, all your last 13 step one's, and we look at everything. Basically, we're looking at kind of like lowest common denominator rules. If you had any category three in your last 13 step one's, you are category three. If you don't have any three's but you have at least one two, you're going to be category two. If you have all category one's in your most recent 13 step one's, then you'll be a category one. That's really what you're doing. You're doing it every week and then you're looking at 13 of those as we go forward. We just keep moving that window across time as we go forward.

All right. Slide 12 just kind of lays out what the performance standards are. Again, they're out of 52. You can divide it to the percent positive and as we'll see in a second we have a way to how we calculate and adjust that to make sure we try to keep it fair to everyone.

Slide 13, starting at the left to right in slide 13, if an establishment magically had exactly 52 samples collected in 52 weeks, we would compare that percent positive exactly to the performance standard. It can happen, right? We have a lot of establishments that it happened to them. Usually, we're in the next two categories. If an establishment happened to have 53 or more samples, which is really a lot like the last one, we're just going to use the percentage. We'll say the percent positive compared to the performance standard and if we look at 10 to 51, they have less than 52 then we'll do what we... we kind of adjust it slightly to try to prevent errors that would unfairly penalize for low volume of samples.

Effectively, we take one positive away and then compute the percent positive and compare that to the performance standard. As I mentioned before, if an establishment has nine or less samples, we would not normally categorize them unless out of those nine samples, they had so many positive that even if we had a negative, they would still be category three. If an establishment has seven comminuted turkey positive or eight chicken parts positive, they're going to be category three even if they only had seven or eight samples because we could add on a couple zeros and it's not going to change anything.

All right, slide 14. I mentioned this before. It's just going in to some more detail, and it's how we adjust it. Again, it's just because the number of samples is smaller, we've heard a lot of feedback from industry especially on the lower side when we get close to 10 where people are concerned. A lot of it just so happened you pull the positive sample a little more frequently than you normally would

have. Like I said before, the way that we try to counterbalance that is we take away one positive and then we compute the percent positive.

Slide 15 then is step two. We got the window for each week one. Now, we're going to get the most 13 recent windows and we're going to see what we can do. Yes, on slide 15, we go through the categories. We've already talked about that. Category three exceeds, category one is never exceeds and category two is in the middle, between 50% of the standard and not. Okay. Slide 16. Let's go ahead and pause there and see if there are any questions.

Selena Kremer: Right. Yes. Aasif, ATT, could you open the open lines for questions?

Aasif, ATT: Absolutely. As a reminder to our audience, if you would like to ask a verbal question through the telephone, please press #2 on your telephone keypad. You will hear notification when your line is unmuted and at that time, please then state your name and question. You're also welcome to submit a written question, please use the chat panel on the lower right-hand side of your screen and address your question to All Panelists. Let's give it a moment.

Todd Reed: Can you also re-provide the notification on how to adjust the URL very quickly. We've had some people that have joined lately and they are on the phone but they haven't heard. If you could just verbally give that instruction once more, it'd be great.

Aasif, ATT: Absolutely. Ladies and gentlemen on the phone, if you have not been able to log in to the webinar, please do copy and paste the link into the browser search bar and adjust the link from ems7 to ems8. The link will start with <http://ems7>. Please change that 7 to an 8. The rest of the link will remain the same. Once changed, you can click enter and you should be able to enter the web conference. If at any time you're having trouble doing so, please press #2 on your telephone keypad and I'd be happy to guide you through that. Otherwise, please call our helpdesk at 888-796-6118.

Todd Reed: All right, thanks. Let's go ahead and get the questions now.

Selena Kremer: I'm only getting one question so far and that's whether or not the webinar will be recorded. Yes, the webinar is being recorded and it will be provided along with the slides on the FSIS website. I'm not seeing any other questions. We can go ahead and move on.

Todd Reed: All right. The next section is just going to be some examples of the exact method that we just talked about. Try to visualize it, because I know for a lot of people hearing is one thing but seeing it makes it a little more clear.

Moving forward to slide 17, we're going to show one, an example of how follow-up sampling has an impact and two, a quick example of how the timing of the *Salmonella* positive during the year kind of influences whether an establishment could move in or out of category two or three..

Slide 18. All right. Slide 18, just to give everyone a second to look at this graphic here, what we're really saying is every blue arrow is a sample that's been collected and if it's got a red star, red means it's positive. It's not a green star. What you can see is this theoretical establishment on the 52-week window had 52 samples with nine positives. The performance standard was eight so this establishment is exceeding the standard in this one week. In this step one, it's going to be a category three for that step one.

Then, moving forward in slide 19 or slide 20, sorry, we can see that if you line up 13 weeks of step one, the example we've just shown, we just looked at is the 13 here. It's week 13. Even though that establishment was not in category three in any of those other weeks, in week 13, if it's category three so then we look at 13 of weeks in a row for step two, this establishment is now in category three. Okay.

Selena Kremer: Question.

Todd Reed: What's that?

Selena Kremer: I'm getting a few questions. I think you might want to take some of them. There is a question, "How is it an establishment can be under category three even when it is beyond the 13-week window?"

Todd Reed: Sorry. Give me a second to think of a way to try to clarify this. Every week, we do step two. Every week, we look at the most recent 13 weeks. If you think of this week, I started this week and I go back 13 weeks. Next week, I would start at next week and when I go back 13 weeks, that kind of cuts right off the front because it adds one onto the end. There's always going to be a 13-week window that applies every single week. It's just as you move forward in time, that interval on the calendar also moves forward. What this means is this is that one week of step one when you have a category three, you're guaranteed at a minimum that one week is going to show up at least 13 times because the next 13 step two's are all going to include that week one. I think that probably answers that.

Going back to other question I can see, but again, it's 13 weeks in a row, we're looking at 13 step one's. If an establishment wants to get out of category three, it has to not have any category three's in the last 13 weeks, in the last 13 step one's. You really got to go forward and show good process control in time to get that.

Stevie Hretz: I was just going to clarify as we're talking about 13 weeks. You're saying about 13 windows and so that 13 steps of 52 weeks each. The illustration that you're looking at, you're actually seeing a total of 64 weeks of sampling because there are things overlapping, 13 sets of 52 weeks each and I think sometimes that's where that question comes from. We're not talking about just 13 weeks of sampling and going back. We're actually going back 64 weeks, which is 13 sets of 52.

Todd Reed: Yes. To piggyback on that in the last question, every time I say window, that window means 52 weeks. Thirteen windows is 13 overlapping 52-week windows, which is exactly where we get to the longer intervals of times.

Selena Kremer: Just a clarification, a couple of clarification questions, “Do you mean 13 windows with each window being 52 weeks?” I think you answered yes.

Todd Reed: Yes. We just went through that.

Selena Kremer: Another question, “My establishment processes for several different establishments under the same parent plan that is already in category two or three. Why is my processing plant retesting the product from these establishments and I already have two samples that came back as positive?”

Todd Reed: That’s kind of a different question, that’s about which product is eligible for sampling at which establishment. I don’t want to dismiss it. It’s an important question, I want to get back to you, but it’s not the focus of today’s webinar. If you could follow up with askFSIS and provide some specific information about your establishment, they would love to get back to you and help you figure that out and explain that situation. I don’t want to get into that today just so that we don’t distract everyone else on this specific topic.

All right. Let’s go ahead and move forward to slide 21.

Selena Kremer: We have another question coming in.

Todd Reed: We’ll move to that one.

Selena Kremer: Okay.

Todd Reed: Let’s get through these slides and then we’ll get to the question. I think once we do a couple more examples, it kind of shows how we get out of it.

Selena Kremer: Okay. Great.

Todd Reed: All right. Yes, this slide 21 is kind of visualizing what we just saw. Again, you can see what category they were for each of the windows, right, so each of the one through 13 is a 52-week window and the 13th week, there was a category three window so this establishment will be in category three, right here.

Then, going to slide 22, we’re going to kind of change gears a little bit and start looking at follow-up sampling and show how follow-up sampling gets to this. Then, after this, is when we’ll explain how to go between categories two and three just to knock it ahead of it.

Follow-up sampling. If we’re looking at this graphic again, you can see where the blue or the samples that were collected and the red are the positives. Okay. On the second row below, you can see where the arrow is really more weak than samples because we have the follow-up samples that got collected and so instead

of having 52 samples, we got 68 samples on the bottom because of follow-up sampling. When you look at the percent positive using those follow-up samples, you can see that it's 9 out of 68, which is 13.2%, which is below that standard, but the other one is 9 out of 52, which exceeds 8, which would be above.

Then, moving forward to slide 23, we can again see how you've got these 13 different kinds of step one's on each row there. You can see how that the establishment got the category three in the seventh window, the seven 52-week window and it's the follow-up samples that took a month for them to get assigned, and we had to wait as we noticed in the policy. Once we got assigned and got collected in the 13th week, you can see they were collected, they were negative, and the establishment, in those weeks, the percent positive slipped below the performance standard.

Again, that's only the step one. The step two is still going to look at all 13 weeks. But what happened is because of the follow-up sample, if the establishment maintained that good process control and keep getting negative, they could get out of category three a lot quicker than had they not have follow-up sampling. It allowed them to get their percent positive down.

Now, I'll answer the question that we just got in writing. You can see it does not necessarily take a whole year to get out of it. It just takes follow-up samples with negatives. In this case, the establishment in this example would probably be around 17, 18 weeks that it would be on category three, give or take a week. I'm just counting off the top of my head but I think that's pretty close.

Stevie Hretz: By this sort of things, 13 weeks. The shortcut to that is once you get one window below category three. Once you've made those effective corrective actions, you know that you have 12 more to go because you got to accumulate 13 category one windows. The shortest possible 13—

Todd Reed: Right. Category one or two. Yes.

Stevie Hretz: Or two. Yes.

Todd Reed: Yes. That's the intent. As soon as you get process control, you get your percent positive down below that threshold, you just got to keep it there consistently. The follow-up sampling helps to make that go faster. Okay.

Moving forward then to slide...

Selena Kremer: I have no idea what just happened.

Todd Reed: One second. All right. Just to confirm before I go forward, can you guys still see the presentation? We had a brief blackout in the room plus we think we are all offline.

Selena Kremer: Asif, ATT, can you still see the presentation okay?

Aasif, ATT: Yes, at this time, the presentation is still being presented online.

Todd Reed: Okay. Great. Apologize everyone for the delay there. Then, yes, slide 24 then is visualizing in a different way than the last slide with the same information about the establishment had those five weeks of category three windows. It's 13 windows that determine the category. It's still in category three as we're going forward.

Okay. Going on the slide 25 then, it's just a theoretical example kind of going again to what we are just saying there. Instead of just looking at 13 weeks, we actually have a few more on the left. You can try to see how the establishment was assigned category three. They took the corrective action. The follow-up samples were collected. The percent positive got down. It was 13 weeks of 52-week windows in a row, they were below category three and then boom, they were assigned category two there on week 24.

We'll keep going. All right. Slide 26 is... we're starting to get into an example of how timing of when positive does have an impact. It's the same type of visualization you've seen before. It got the positive distributed. You've got the follow-up sample. Then, if we go forward to slide 27... I think we've lost the visualization on that. Go back one more. All right. You're not going to see the visualization. I'm going to talk through it so that slides 26 and 27 makes sense. The column of under May where you've got the positive samples, on the next slide, theoretically, if those positives had not been in May but had been earlier in that calendar year, then when that establishment moved between categories, we change factors because the positive sample would go out of that 52-week moving window with a different time. An example that I'm trying to illustrate is that when the positive happened, it does have an impact.

Going forward on the slide 27, it's just showing that things could happen sooner because that positive was sooner so the establishment would move out of category three sooner. Okay. Get the slide 28, we're going to pause. We got a few written questions that came in. I'll try to address those and then we'll open up the questions on the phone as well.

Selena Kremer: Okay. "Why would a for-cause FSA be initiated immediately upon an establishment moving into category three status when follow-up sampling isn't scheduled for 30 days after the categorization? Wouldn't it make more sense to wait until after the follow-up sampling is conducted and the results reported?"

Rachel Edelstein: We're in the process of getting instruction out to the field concerning when to do an FSA and when to do a PHRE and we'll be updating stakeholders in the next week or so then we'll get the instructions out. Currently, what we're thinking now is that there would be a PHRE to determine whether do that FSA. We'll get clarifying instructions out on that issue.

Selena Kremer: Thank you. Our next question, “Why do 13, 52-week windows instead of a 65-week percentage?”

Todd Reed: That’s a great question. The straight up answer is that’s how it was put together and it’s how in the *Federal Register* so we need to go with it. Mathematically, it’s the same. It’s a linear transformation so for those of us that wrote it; it was easier to think of it this way. If that’s how you choose to think of it, I think mathematically it’s the same.

Selena Kremer: Okay. Our next question, “While the plants reduce—”

Todd Reed: I guess, one thing to add to that response before I go forward though, remember an establishment can get category three based on their very most recent 52-week window where we’re going off either the number of samples or that percentage and so if we were going on 65, that might give us a different calculation. I guess I retract my previous answer. You get a slightly different thing. You can get a slightly different answer on a 52-week window. Normally, it would be almost the same but there are cases where it would be different. Apologize for that misstatement.

Selena Kremer: Thank you. Our next question, “While the plants reduce their percentage with follow-up samples to just below category three status, they would have to remain at zero positives for several months for this to work. Is that a realistic expectation given that they were having a positive every two to three months even when under better process control?”

Todd Reed: To get the quickest transition from category three to out of category three, you definitely want zero positives. The performance standard isn’t zero. The performance standard does allow some number of positives. As long as the rate of the positives that an establishment gets across the year doesn’t exceed that performance standard, you can still move out of the category. It just would not be as fast.

Selena Kremer: Thank you. Do we have any questions on the phone?

Aasif, ATT: Ladies and gentlemen, as a reminder, if you would like to ask a question over the phone, please press #2 on your telephone keypad. Once again, it was #2 on your telephone keypad. Looks like we have received one question in the queue and that caller’s line has been unmuted. Caller, if you are saying it, you might have hit mute on your phone as well.

Todd Reed: We can’t hear your question coming through.

Unidentified

- Speaker:** Okay. Tell me what's the rationale of looking at the last 13 weeks and if I have 12 weeks of one or two category, for example, I meet one or two but one week of category three, why is the plant classified as category three?
- Todd Reed:** I guess the first thing I would say is remember each week is really a window of 52-weeks so it's not really looking at one week where you're in category three. It's a 52-week window where an establishment was in category three. The reason we want to look at 13 windows in a row is to make sure that your process control is consistent and then the establishment is maintaining that and is not yo-yoing back and forth across categories.
- Selena Kremer:** Thank you. We have another... a couple more written questions. "How quickly can a plant get out of category three best case scenario?"
- Todd Reed:** The 13 weeks would be the best-case scenario. If you had a positive or two in that very first week and they dropped off with negatives the following week.
- Selena Kremer:** "When you say window, does that say one week or 52 weeks?"
- Todd Reed:** A window is calculated every week but it covers 52 weeks of data.
- Selena Kremer:** "FSIS is currently requesting the plant's internal *Salmonella* results prior to an FSA. How is this data used and does it remain confidential?"
- Rachel Edelstein:** We just want to clarify, I mean FSIS can look at plant data that has a bearing on the plant's HACCP or sanitation at any time. This is just part of FSIS looking at plant data; we have instructions for inspectors to look at that data on a weekly basis in Directive 5000.2. Of course, it does remain confidential. FSIS is not sharing that data with anybody else.
- Selena Kremer:** Thank you. I'm not seeing any other questions. Todd, we can move on to the next section if you're ready.
- Todd Reed:** I think another one just came through.
- Selena Kremer:** There is another question, "Are local FSIS management personnel trained to field questions in relation to this categorization methodology when category two and/or three status' result?"
- Stevie Hretz:** Specifically, for a detailed illustration or individual assistance with that, we welcome those inquiries through askFSIS and we will happily dive right into the process and walk you through the progression. That way, we can help establishments plan accordingly or understand fully how they got into that category.
- Selena Kremer:** Okay. Thank you.
- Todd Reed:** Yes. All right. Let's go ahead and we'll move forward and this is our last section and it's really about communications and how we're sharing the information. I saw another question came through. We'll hold that and I'll get some more

questions at the end once we're done. We'll just get through these last few slides and then we'll be open for questions.

The first way that the categories are reported are through PHIS reports and both the inspectors in plant can pull those reports and get them as well as the establishments that are registered to use PHIS can also pull those reports. You can view the establishment category that way.

The establishment category as of that exact time is published in the quarterly establishment letter that gets sent out with all the sampling results. But again, that's only once a quarter so it doesn't update it frequently. PHIS alerts are sent to inspectors and district officials when the establishment is assigned to category three and two. Inspectors are to convey that information during the weekly meeting. We're really getting this information out multiple ways.

Slide 30, we do individual category postings right now. As you're probably aware, we post categories by establishments per carcasses, both chicken and young turkey on the FSIS website. Moving forward, slide 31, we also do aggregate categories for carcasses as well as parts and comminuted on our website right now. Those get published on the FSIS website on the regular basis. Slide 32 or 34. Going forward, starting in November 2018, FSIS will post a template for raw chicken parts and comminuted poultry and begin posting establishment categories after Thanksgiving. That's what we're going to do in the future. This is part of our ongoing strategy to address *Salmonella* and *Campylobacter* control in establishments producing raw poultry products. It's consistent with our *Federal Register* notice of February 2016.

All right, slide 35, there are some additional resources, which I'm not going to read out, but you can get them off the presentation and you can always, again, use askFSIS, which is a great resource for plants if you have questions. As we mentioned in the beginning, this presentation will be posted on the FSIS website and will be available. Then, slide 36, that's it. At this point in time, we're going to be open for questions. We've got a couple of written questions that we'll start with and then we can take it from there.

Selena Kremer: Okay. Before we get started, Aasif, ATT, can you go through the instructions for the phone one more time for them to call in?

Aasif, ATT: Absolutely. Ladies and gentlemen, if you would like to ask a question through the telephone line, please press #2 on your telephone keypad. You will hear a notification when your line is unmuted. Please then state your name and question. Once again, it was #2.

Selena Kremer: Thank you.

Aasif, ATT: It looks like we have received a question over the telephone line.

Selena Kremer: Great. Go ahead.

- Aasif, ATT:** Caller, your line has been unmuted.
- Nicole:** Yes. It's Nicole. We are a small plant so do you guys subtract one for the report?
- Todd Reed:** Based off the number of samples collected, if you're a small plant, then you probably have less than 52 samples collected in the category. Assuming that's the case, then yes, we would select one positive when we do the calculations.
- Nicole:** Okay. Thank you.
- Todd Reed:** Or one sample. One sample.
- Selena Kremer:** Okay. We have a written question here. "IPP are putting data results in weekly meeting notes including their own calculations. Is that acceptable?"
- Rachel Edelstein:** We, in our instructions or the latest follow-up sampling instructions, we instructed inspectors not to do the calculations on their own. If the category is available, it should be... it's available through PHIS so we'll just work with OFO to clarify as necessary. Thank you.
- Selena Kremer:** "If routine samples are taken once a month and follow-up sampling is once a day, would it still be 13 weeks in that case scenario to get out of category three?"
- Todd Reed:** The answer to that is yes because if you remember step two, it's looking at the most recent 13 step one's. That original step one, that very first one, the establishment was in category three, so no matter how many negative samples start the following day, then it still takes a minimum of 13 weeks for that very first step one, that 52-week window, to age out.
- Selena Kremer:** Thank you. Next question, "Will the first posting still reflect what would have been posted on November 20?"
- Roberta Wagner:** They are talking about the comminuted and parts.
- Todd Reed:** You mean when we post in November?
- Roberta Wagner:** Yes.
- Todd Reed:** I believe the answer is yes, but what we post will precisely explain what dates it covers. We haven't done it yet, it's in the future, but yes.
- Selena Kremer:** Thank you. Then, we did get another question about the slides and the recording, and yes, those will be posted on the FSIS website. This webinar is being recorded and the slides will be made available. Our next question, "Does the—"
- Carol Blake:** It will be on the Meeting and Events page.
- Selena Kremer:** Next question, "Does the data transmitted to FSIS by those plants that participate in the *Salmonella* Initiative Program play any role in the categorization scheme?"
- Todd Reed:** No, they do not.

- Selena Kremer:** Okay. Thank you. Our next question, “Frequency, is it based on the average daily volume listed from a raw intact parts category in the establishment profile or the raw intact parts category plus the raw non-intact parts category? For example, the plant may have an average daily volume of 3,000 pounds of intact parts and 500,000 pounds of non-intact parts. What volume will you use?”
- Nelson Clinch:** All of the eligible products are taken into consideration. Both of those would be used and whichever has the higher average daily production is the average daily production that will be used in assigning samples for that establishment for the upcoming month.
- Selena Kremer:** Thank you. Our next written question, “Will the data set documenting all samples currently being posted quarterly ever be posted monthly? If the category assignments are being published monthly, why can’t the data set on a per sample basis be posted monthly as well?”
- Todd Reed:** That is about logistics and the resources internally. As we posted in the Federal Register referring to our data policy and plan, those data sets are posted quarterly. That’s the process we’re going to keep following.
- Selena Kremer:** Thank you. Our next question, “Can you please confirm if the oldest result that would be included in the moving window would be from 52 weeks ago and no older than that?”
- Todd Reed:** To be clear, any time a window, one of those 13 weeks is calculated, it’s 52 weeks of data, but the step two uses the most recent 13 step one’s. Thirteen weeks ago, step one, that window is 52 weeks of data as of 13 weeks ago. It’s really 52 weeks plus 13 weeks for the oldest window.
- Selena Kremer:** Thank you. Our next question, “For a small plant with 12 samples in 52 weeks having three positives, would calculation be two out of 12 or two out of 11?”
- Todd Reed:** It would be two out of 12.
- Selena Kremer:** Our next question, “To clarify the November posting question, it’d be the same 13-week time period as would have been reviewed for November 20 meaning ending on the last Saturday of October?”
- Todd Reed:** Yes.
- Selena Kremer:** Thank you.
- Todd Reed:** That is our intention but again, when we post, we will explicitly say what date there is just to make sure there isn’t any confusion by the time we did the calculations.
- Selena Kremer:** Thank you. Our next written question, “My establishment is a small plant but it just started testing on a monthly basis and has two positives. How long it will take for them to be listed in a category?”

- Todd Reed:** Once you get the 10 samples and once you hit that 10-sample threshold then that calculation can happen. I can't say exactly how much time it would be. It's more how many samples.
- Selena Kremer:** Thank you. Next question, "If a company does not have a *Salmonella* Initiative Program-based waiver, is there any requirement for a company to do their own sampling if it has no bearing?"
- Rachel Edelstein:** If it's a slaughter establishment, all slaughter establishments have to do testing under the Poultry Modernization Rule. If it's not a slaughter establishment, they're not required to do testing but FSIS would look for them to have some kind of verification that their system is working.
- Selena Kremer:** Thank you. Our next question, "When will the serotype information be included in the database documenting all samples collected?"
- Todd Reed:** That's still to be determined.
- Selena Kremer:** Okay. Next question, "Can you please again define the difference between a small and a large plant?"
- Todd Reed:** In order to avoid confusion, when we're doing establishment categories, it's based on the number of samples that are collected, which is based on production volume. Instead of defining a small or large plant, which we could but we'd confuse things, I would say instead look at the production volume and as we said in the beginning of the presentation, establishments who produced a higher volume get assigned more samples. It's really the number of samples that matter not whether an establishment would be considered small, or very small, or large.
- Selena Kremer:** Okay. Our next question, "Just to clarify, will the parts categories only be posted quarterly as opposed to monthly like the whole bird categories?"
- Todd Reed:** They would be monthly. Wait. Yes. Just to clarify all of the categories are monthly.
- Selena Kremer:** All right. Great. Thank you. Our next question, "If an establishment continued to be category three, even after follow-up sampling, what actions will be taken by FSIS?"
- Todd Reed:** Actually, for today's presentation, we're talking about sampling and how samples are assigned and we're not going into that. I would look at the *Federal Register* notice and the policies for guidance on it.
- Roberta Wagner:** There will be notice.
- Rachel Edelstein:** Remember, that's what I was talking about before with the questions about the FSAs. We'll get a notice out that will be giving those instructions to inspectors.
- Todd Reed:** All right. Thank you.

Selena Kremer: Okay. Great. I think we have a question on the phone.

Aasif, ATT: Caller, your line has been unmuted.

Speaker 6: When are these being posted?

Todd Reed: November 2018 will be the first time we're posting the categories for comminuted and parts. The carcass categories have already been posted and will continue to be posted.

Selena Kremer: I am not seeing any more written questions. Do we have other phone questions?

Aasif, ATT: As a reminder, if you do have a question that you would like to ask through the telephone line, please press #2 on your telephone keypad. Once again, it was #2 on your telephone keypad. We'll just give it a moment. At this time, we have no other questions on the telephone line.

Selena Kremer: Great. And, I am not seeing any more written questions either. With that, I want to thank everyone for their participation today and as a reminder, we will be posting the presentation as well as the recording from today's webinar on the FSIS website – Meeting and Events page. With that, everyone, have a great afternoon and thank you.

Todd Reed: Thanks everyone.

Aasif, ATT: Thanks for all for joining today's conference. The conference is now concluded and you may now disconnect.

[END OF TRANSCRIPT]