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Swine Modernization Webinar: March 22, 2018, 1-3 p.m. ET

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Rita, ATT: Welcome and thank you for joining today's conference Swine Modernization, please note that all participants lines will be muted until the Q&A portion of the call. We'll provide you with instructions on how to ask a verbal question at that time. You are welcome to submit written questions during the presentation and these will be addressed during Q&A. To submit a written question, use the chat panel on the right-hand side of your screen, choose "All Panelists" from the send to drop down menu. With that I'll turn the call over to Melissa Hammar from the Office of Policy and Program Development. Please go ahead.

Melissa Hammar: Okay. So, we had proposed to our establishments that slaughter market hogs to operate under New Swine Inspection System, the New Swine Slaughter Inspection System. We proposed…the proposed rule on February 1 and the comment period ends on May 2nd. Under the proposed rule market hogs slaughter establishments that do not choose to operate under the New Swine Inspection System may continue to operate under traditional inspection. The agency is also proposing the several changes to the regulations that would affect all establishments that slaughter swine regardless of the inspection system under which they operate or the age, size, or class of swine. Okay, go back.

Cody Kahlig: Oh, go back?

Melissa Hammar: Yeah. So, under traditional inspection, most market hog establishment, voluntary segregate animals before ante-mortem inspection. So, they separate normal animals from abnormal animals before FSIS performs ante-mortem inspection. Establishment personnel conducts no postmortem or any activities under traditional inspection. So, FSIS inspectors check each carcass for defects and direct plant employees to take corrective actions. FSIS public health veterinarians (PHVs) condemned carcasses with animal diseases and plant employees dispose of condemned carcasses. FSIS inspectors spend too much time inspecting for non-food safety defects like scabs and bruises that are related more to the marketability of the product.

So, this is a diagram of the ante-mortem sorting or sorting before ante-mortem inspection. The Market Hog establishment personnel segregate animals again that appear normal from animals that appear abnormal and this happens in the lairage pens. So, we require these establishments to document their segregation procedures in their HACCP plans or prerequisite program. FSIS inspectors examine all animals found by the establishment to be normal at rest, and five to ten percent of those animals in motion. If any animals exhibit signs of condemnable conditions, FSIS inspectors direct establishment employees to move the animals to the "U.S. Suspect" pens for final disposition by the FSIS PHV.

The FSIS PHV examines all market hogs in the U.S. Suspect Pen. The PHV classifies the market hogs as 1) passed for slaughter, 2) U.S. Condemned or 3) U.S. Suspect. FSIS inspectors observe establishment employees performing segregation procedures at least once per month.

Melissa Hammar: Okay. This is a diagram of postmortem inspection under traditional inspection. There's up to seven online inspectors and one offline inspector. The whole process is overseen by one FSIS public health veterinarian. FSIS inspectors conducting online activities spend most of their time, more time than they should, looking for obvious visual defects like bruises, which affect the appearance but not the safety of the product. The FSIS offline inspector conducts additional food safety related activities such as verifying that establishment's processing meets their HACCP critical limits and verifying whether sanitation SOPs are effective.

Next slide. This is what an inspector sees in PHIS, this is how they record the U.S. condemn tag and any condemned the animal. This can be a time-consuming process because under traditional inspection FSIS inspectors have to enter every condemn tag into PHIS. We believe more FSIS resources could be devoted to offline inspection activities of initial sorting and tagging function where performed by establishment personnel.

Ok, next slide. So, need for modernization, traditional inspection was developed before the HACCP regulations, and before the agency began targeting its resources to address public health risks associated with foodborne pathogens. Advances in animal science, market hog production systems, biosecurity and veterinary medicine have eliminated the vast majority of diseases that we inspect for under traditional inspection. Under traditional inspection, inspectors are required to send a large amount of time conducting inspection for quality related defects rather than verifying food safety related process control and determining the effectiveness of the HACCP systems. Traditional inspection also limits lines speeds and restricts an establishment's ability to re-configuring and consolidate lines.

Melissa Hammar: Next slide. Okay. So, we developed this proposed rule based on the agency's experience under the Hazard Analysis and Critical Control Point (HACCP)-Based Inspection Models Project otherwise known as HIMP. HIMP was developed in 1997 to: improve food safety and the effectiveness of inspection systems; reduce the risk of foodborne illness in the U.S; remove unnecessary regulatory obstacles to innovation; and make better use of the agency's resources. We initiated the HIMP pilot in 20 young chicken, five young turkey, and five market hog establishment for a waiver basis**.** Under HIMP, 30 activities shifted from FSIS inspectors to establishment personnel. So, before FSIS ante-mortem inspection, establishment employees sort carcasses and parts, and trim dressing defects and contamination, like hair, bruises, feces, ingesta, and milk. Establishment employees also mark with ink localized pathology defects intended for removal under FSIS supervision and they tag carcasses and parts

intended for disposal under FSIS supervision. Establishments are required to implement process control plans and meet food safety and other consumer protection (OCP) performance standards. FSIS inspectors still conduct 100% ante-mortem and 100% post-mortem inspection.

Melissa Hammar: Next slide. Okay, so this, these are the model performance standards for market hog plants for food safety. So, before implementing the HIMP project, an independent consulting firm, Research Triangle Institute (RTI) collected baseline organoleptic and microbiological data in the five market hog slaughter establishments that volunteered to participate in the HIMP program. These data reflect the performance of the establishments under traditional inspection and provided the basis to establish HIMP performance standards for food safety defects and non-food safety ``Other Consumer Protection'' (OCP) defects.

So, FSIS established three categories of food safety related performance standards under HIMP for these conditions: ``Food Safety-1'' addresses infectious conditions like septicemia, toxemia, pyemia, and cysticercosis; ``Food Safety -2'' addresses contamination from fecal, ingesta, and milk; and ``Food Safety -3'' addresses certain conditions identified at ante-mortem like moribund, pyretic, and if the animal has any neurologic conditions. We set all three of these at zero. We have a zero tolerance policy for food safety conditions.

Next slide. These are our OCP performance standards. So we based these on the performance level of establishments representing the 75th percentile for each category. FSIS established three categories of OCP performance standards for various types of trim and dressing defects that primarily affect the quality of products: ``OCP-1'' addresses carcass pathology defects, ``OCP-2'' addresses visceral pathology defects, and ``OCP-3'' addresses miscellaneous defects. To participate in the program, establishments operating under HIMP are required to maintain process control plans to meet the performance standards for food safety and non-food safety OCP defects. It should be noted that in the HIMP report, HIMP establishments did not have a problem meeting these standards.

Next slide. In the proposed role, we explain that under HIMP inspectors conduct at least 24 carcass checks per shift for OCP defects. This chart explains, like if they conduct 24 checks and any defects were found they are able to conduct more carcass checks and it explains when FSIS would issue an NR if defects were found. And then NR is a non-complaint carcass. Okay, and again as I mentioned HIMP establishments rarely fail these OCP standards.

Next slide. This is an example of ante-mortem sorting and ante-mortem inspection under HIMP. So, similar to the voluntary segregation procedures that we have under traditional inspection. Establishment personnel sort animals before they are presented to FSIS ante-mortem inspectors. So, again, like the normal and healthy animals are sorted into the normal pens, the abnormal animals or animals that appear to have disease conditions would be sorted into

the subject pens. The plant can also reject animals and this is all very, very similar to traditional inspection. The main difference is that, the establishment have to have an OCP for food safety conditions before stunning. The FSIS PHV verifies that and if any establishment does not properly sort animals, they will receive a noncompliance record.

Next slide. This is a diagram of post-mortem inspection under HIMP. So, there are two offline inspectors, one public health veterinarian, and then there is an online inspector at the head, viscera, and carcass inspection station. There are plant sorters that sort and remove and trim defects before FSIS inspectors look at the head, carcass, and viscera**.** So, because establishment employees are required to sort and identify defects before FSIS inspection, zero adulterated carcasses and parts are presented for FSIS inspection. As a result, FSIS can assign fewer inspectors to online inspection putting up agency resources can conduct more offline activities such as HACCP and sanitation SOP verification procedures. FSIS can conduct more offline human verification activities under HIMP.

Next slide. These are just some examples of how establishments mark or identify defects with ink and then also if you're able to zoom in one of the hog has a tattoo that's just another example of how establishments under HIMP are able to identify these excellent animals. Next slide, okay so this what an FSIS inspector sees in PHIS under HIMP. The establishment is required to keep totals of animals that are sorted and removed during animal ante-mortem and post-mortem and at the end of the day they give these numbers to the FSIS inspector. So, the FSIS inspector analyzes the total in the PHIS. If FSIS, on the very rare chance that FSIS has to also condemn animals, FSIS will enter those U.S. condemn tags individually into PHIS. But, overall the sorting brings down the number dramatically so FSIS inspectors don't have to spend as much time entering individual tags.

Next slide. So, there's been some questions over who can stop the line and when they can stop the line. Who can stop the line? Online and offline inspectors and the public health veterinarians can stop the line. They can stop the line when they find an insanitary condition, contaminated organs, parts that will create an unsanitary condition or interfere with inspection. When online IPP find a zero tolerance defect that the final rail or when there is an immediate personnel safety concern.

Next slide, so who can slow the line? Only the public health veterinarian can slow the line. The line can be slowed down when there is excessive disease or OCP defects, when there is deficiencies in carcass presentation that can affect FSIS' ability to adequately inspect and the samples of those that are missing organs or parts, excessive contamination, or evisceration errors**.** Next slide, so HIMP does not change the way FSIS verifies and enforces the Humane Methods

of Slaughter Act. We still perform HATS or Humane Activities Tracking Systems and these are the nine categories that we verify during those offline activities.

Next slide. Okay, so the HIMP report did not address compliances in the Humane Methods of Slaughter Act but we reviewed HATS task data in PHIS from January 2013 through September 2015 and compared the number of offline humane handling activities performed in five HIMP market hog establishment in the same 21 comparable large non-HIMP market hog establishment that FSIS used in the HIMP report. We found that FSIS inspectors spent more time verifying humane handling activities in HIMP establishments than they did under traditional inspection. The FSIS inspector devotes approximately 5.33 hours per shift to verifying humane handling activities for HATS categories than HIMP as opposed to 4.29 hours per shift in the market hog HIMP establishment.

We also compared the rate of humane handling NRs issuing HIMP market hog establishments and non-HIMP market hog establishment. FSIS inspectors also documented fewer humane handling NRs in HIMP market hog establishments than in non-HIMP market hog establishments. From 2013 to 2015, FSIS recorded 11 humane handling NRs in five HIMP market hog establishments and 117 NRs in the 21 non-HIMP market hog comparison establishments. In those 11, we did not find any evidence of market hogs being forced to move faster than normal walking speeds to keep up with faster evisceration line speed. We think this data demonstrates that HIMP establishment have a higher compliance of humane handling regulations than non-HIMP establishment in that increased offline inspection may improve compliance of the Humane Methods of Slaughter Act.

Okay, next slide. So, in 2014 we posted the market hog HIMP report and the key questions we asked in the HIMP report, "Are HIMP market hog establishments have any contamination as well as non-HIMP market hogs establishments?" and "Are HIMP market hog establishment meeting the food safety and OCP performance standards?" And key components of the assessment are the selection of comparable non-HIMP market hog establishments, evaluation and incorporating multiple FSIS data sources including inspection data, regulation and verification and noncompliance associated with public health related regulations and microbiological and residue testing data as well as food safety and OCP records.

Next slide. So the HIMP report found that that HIMP slaughter systems are performing as well as other systems under traditional inspection. The data indicate nearly comparable performance between HIMP and non-HIMP, more offline tasks are being performed in HIMP plants, as well as noncompliance rates observed in HIMP plants, less frequent observations includes these related concerns such as fecal contamination, septicemia, toxemia, in HIMP plants. Similar rates in *Salmonella* detection and the HIMP report often found that sorting rates in HIMP were similar to the condemnation rates in non-HIMP

establishments. As I mentioned before, the HIMP report found that these establishments were meeting OCP performance data.

Lindsey Ward: Hallo, my name is Lindsey Ward-Gohkale from the Risk Assessment and Analytics Staff at FSIS and I'm going to be talking about the market hog risk assessment. Could you please go to the next slide? Separate from the HIMP report and in order to better understand the public health implication of reallocating inspection tasks to more offline procedures, FSIS carried out a quantitative microbial risk assessment in which multiple scenarios were considered. Three category-specific scenarios were created, each of which included adjustments to a single inspection procedure category. The fourth scenario was created to estimate the impact of adjusting all procedure categories simultaneously as being in market hog HIMP**.**

Next slide. The risk assessment was structured as a two-stage prevalence-based risk model incorporating data from FSIS' *Salmonella* sampling program and from FSIS' inspection procedure record at all market hog plants. The first phase of the model, a regression analysis, determined the strength and significance of the relationship between FSIS inspection procedures and percentage of *Salmonella* positive market hog carcass samples, which we use as an approximation of contamination prevalence. In a second stage, the aforementioned scenarios were constructed in a simulation model which produced estimates of market hog attributable *Salmonella* illnesses under the hypothetical offline inspection procedure scenarios. The contamination prevalence to human illnesses relationship has been previously published by FSIS scientists.

Next slide please. This risk assessment estimated that increasing offline inspection task rates in non-HIMP establishments was most likely to result in a reduction in human *Salmonella* illnesses relative to the yearly baseline estimate of 69,857 from the CDC. The three category-specific scenarios resulted in illness reduction of 1,257 cases, 506 cases, and 770 cases. The combined scenario resulted in the most likely illness reduction estimate of 2,533 cases.

Next slide please. Overall the risk assessment improved the agency's understanding of the public health impact of different inspection activities and hog slaughter facilities particularly that a new swine inspection system (NSIS) with increased offline inspection procedure rates would lead to reduction in *Salmonella* contamination and illnesses, most likely around 3.6%.

Melissa Hammar: Next slide, we are going to go over the key elements of the proposed NSIS. Okay, so under the proposed rule and consistent with the HIMP program, FSIS would be requiring establishment personnel to sort and remove unfit animals before FSIS ante-mortem inspection, trim and identify defects on carcasses and parts before FSIS post-mortem inspection. Any identify animals or carcasses that have been sorted or removed before FSIS inspection with a unique tag, tattoo, or similar device and immediately denature all major portions of the carcass onsite and maintain records to documents the total number of animals and

carcasses sorted before FSIS ante-mortem and post-mortem inspections per day. We are also proposing to require establishments to immediately notify FSIS inspectors that they suspect the animals or carcass is reported with a foreign animal disease. I just want to be very clear that these are very, very rare conditions; market hog are young healthy animals, this is just another layer of protection because under traditional HIMP or NSIS, sorters see the animals first so they are in the...this would just create a requirement to notify FSIS as soon as possible.

Next slide. Go back one more. So, we'll be shifting agency resources to conduct more offline inspection activities that are more effective at ensuring food safety to allow for two offline verification inspectors per line per shift and would reduce the number of online inspectors to a maximum of three per line per shift. We are proposing to require establishments to maintain records, documenting that products resulting from any definition of ready-to-cook, which would be defined as any slaughtered pork product free from bile, hair, scurf, dirt, cloves, toenails, claws, bruises, edema, scabs, foreign material, and odor, and which of these is without need of further processing**.** Finally, we are revoking maximum line speeds in establishments to determine their own line of speeds based ability to maintain process control.

Next slide. So, this is a diagram of sorting an ante-mortem inspection under NSIS. It's pretty much the same thing as what we presented earlier under HIMP. Again, the establishment will sort normal from abnormal animals. Abnormal animals will go in a subject pen and they will be subject to closer FSIS inspection. FSIS inspectors still have the authority, to put animal in the U.S. suspect pen and again there's a zero tolerance for food safety conditions and if the establishment does not do a good job sorting, they will get a noncompliance record. As part of our offline tasks, we verify humane handling and we also verify sorting procedures at least two times per shift. And during that time, we make sure that animals are euthanized humanely and not...animals that are satisfied to be transported to other traditional inspection establishments, are healthy, and ready for transport. Another point I want to make clear is that animals that are sorted into the reject pen, these animals are most likely going to another traditional establishment so they will, and under traditional inspection, they will also be seen by an FSIS public health veterinarian.

Next slide. Very similar to HIMP, again, there will be two offline...in most establishments, there will be two offline inspectors and three online inspectors - one at head, viscera, and carcass. However, we did provide more flexibility in the proposed rule to give establishments more flexibility over their production process so establishments have the ability to reconfigure their lines if they decide they want to change the way the head, viscera, or carcasses are presented - to improve the ergonomics, their process control and to maintain optimum line speeds**.** So, again FSIS will inspect the head, viscera, and carcass of each animal; however, establishments may reconfigure their lines so that a

presenter ready to inspect heads with their carcass for post-mortem inspection at one location, or in two locations, or three locations. FSIS would assign one to three inspectors to conduct online activities depending on the needs and line configuration. These inspectors would rotate to conduct offline inspection activities.

We did say in the proposed role that we would assign one inspector, only if, the agency had data and experience to ensure that the one inspector is able to conduct all online post-mortem inspection activity. For most establishments that currently operate under traditional and have inspection stations set up at head, viscera, and carcass, this is what we would expect them to look like, but the rule does give them flexibility - like there's one HIMP establishment that has combined the viscera and carcass inspection stations, so there's only two online inspectors. So, under the proposed rule they do have flexibility to make some changes.

Next slide. This is just a summary of traditional versus NSIS. So, again traditional is based – was developed before HACCP - and NSIS is based on HACCP principles, so we require establishments to identify hazards earlier and at various point in the slaughter production process. Both traditional and NSIS allow establishments to sort live hogs before FSIS ante-mortem inspection. Those conduct 100% ... FSIS conducts 100% inspection under traditional and under NSIS, FSIS would conduct 100% post-mortem inspection. Again under both systems, only FSIS PHVs can condemn the animals, carcasses, and parts.

Next slide. Okay, so under NSIS we are requiring establishments to identify defects and trim these carcasses and parts before FSIS post-mortem inspection. This would allow us to conduct a more efficient inspection than under traditional. Under NSIS, we will allow establishments to consolidate its inspection stations or otherwise reconfigure their evisceration lines in order to make room for more innovative and automated equipment, and we will allow establishments operate at faster line speeds only if they are able to also maintain process control.

Next slide. Okay, so in addition to propose an NSIS we are also proposing changes for all swine slaughter establishments.

We are proposing to require all official swine slaughter establishments to develop and implement and maintain in their HACCP system written procedures to prevent a contamination of carcasses and parts, and enteric pathogens, fecal material, and adjust the amount throughout the entire slaughter and dressing operation. These procedures must include sampling and analysis for microbial organisms to monitor process control for enteric pathogens and will have written procedures for visible fecal material, ingesta, and mild contamination. We are proposing to remove the current requirements of test for generic *E. coli* and to monitor process control and replace them with the new testing requirements described above. The new testing requirements will allow

establishments to develop sampling plants are more tailored to the specific establishment that's more effective in monitoring their specific process control that the current generic *E. coli* criteria. We are also proposing you remove the codified *Salmonella* reduction pathogen and performance standards because we've stopped testing for them.

Next slide, so we've proposed a minimum frequency with which establishments would be required to collect samples. They would be required to collect samples - one at pre-evisceration and one at post-chill - or for various small and very low volume establishments a single post-chill sample. So, establishments, except for very small and very low volume establishments, would be required to collect pre-evisceration and post-chill samples at a frequency of once per one thousand carcasses.

Very small and very low volume establishments will be required to collect at least one sample during each week of operation in each year, if after consecutively collecting 13 weekly samples, very small and very low volume establishment can demonstrate that they are effectively maintaining process control, they can modify their sampling plans to collect samples less frequently. The proposal allows establishments to substitute alternative sampling locations and alternative sampling frequencies. The proposed sampling frequencies reflect the frequencies that are currently in the generic *E. coli* regulation.

Next slide. We are also proposing to require establishments to develop, implement, and maintain in their HACCP system written procedures to prevent contamination of the pre-operational environment by enteric pathogens. The pre-operational environment includes food contact surfaces, pre-slaughter and equipment, including knives, in edible food production departments before slaughter operations begin. This is a new, novel proposed requirement that we extend to other species in subsequent rulemaking, depending on comments, and whether we are able to finalize and implement the requirement. So, these procedures include sampling analysis for food contact surfaces in the pre-operational environment from microbial organisms to ensure that the surfaces are sanitary and free from enteric pathogen. The sampling frequency must be adequate to monitor the establishment ability to maintain sanitary conditions in the pre-operational environment.

Next slide. Okay, and this is just a reminder, that we posted two draft compliance guides on our website related to the proposed rule, so we have a compliance guide on training sorters and we have a compliance guide on all the proposed sampling requirements. We are asking for comments on these compliance guides.

Okay. Next up is Andrew Pugliesi from our Policy Analysis Staff.

Andrew Pugliese: Hello, as Melissa just said, my name is Andrew Pugliesi and I'm with the Policy Analysis Staff. I handle the economic review for this proposal to which we use

2016 as a base year. During 2016 when we approximate 612, I'm sorry, next slide, we used 2016 as the base year for this rule, during which there were approximate 612 swine slaughter establishments under federal inspection, at which approximate 118 million hogs were slaughtered. Of these establishments, 40 were exclusively slaughtering market swine and were considered high volume and account for 92% of production. These establishments we assumed will participate in NSIS. Remaining 532 establishments, slaughtered a variety of swine sub classes or mix of high and low volume and account for less than 8% of production.

Next slide. So, broadly speaking, this rule had two types of costs - voluntary and mandatory. The voluntary cost were associated with the NSIS process and had an approximate cost of 17.02 million dollars assuming at 3% discount rate over 10 years. This costs are largely associated with the need for additional labor to conduct online sorting which had an estimated cost of 16.62 million dollars. In addition to this there are some additional labor costs associated with meeting the ready-to-cook standards which on estimate cost of 398 thousand dollars annually. If costs were incurred exclusively by the 22 large and 13 small high volume establishments expected to adopt NSIS. It's worth pointing out that the five large HIMP establishments have likely already incurred these labor costs and so there is no new additional cost associated with joining NSIS.

Next slide please. So, the second broad cost category are associated with the mandatory portion of the rule, which came in at about 881 thousand dollars annually. Again, assuming a 3% discount rate over ten years. Dropping down in a little more detail about 1.5 million dollars were associated with written sanitary dressing plans or developing and implementing a sanitary dressing plan. There was actually a cost saving associated with changes to modernizing the process control program, I believe cost savings were estimated at 766 thousand dollars and then there's also some cost associated with sampling the slaughter environment for microbiological contamination which are an estimated cost of 81,000 dollars. These costs are associated with all swine slaughter establishments.

Next slide please. The economic analysis also quantified economic value of the proposal, the expected health benefits and benefits from increasing industrial efficiency. Based on the hog risk assessment, which estimated for the 35 establishments that are expected to convert to NSIS. If they were to do so, NSIS would reduce number of humans illnesses, attributed to products derived from market hogs when average of about 2,533 *Salmonella* illnesses annually. So, the potential cost to reduction of 9.33 million dollars annually.

With regards to industrial efficiency, based on the HACCP-inspection Models Project, for market hogs, the HIMP establishments' average line speeds were approximate 12.5% faster than comparable establishments. Assuming all 35

establishments expected to adopt NSIS increase their line speeds by this amount, initial benefits are about 47.3 million dollars annually.

Next slide please. Our analysis also included the expected impacts to as agency budget.

NSIS is expected to reduce agency budgetary needs by roughly 6.38 million dollars. Again, assuming a 3% percent discount rate over 10 years. Exchanges taken into consideration changes in agency staffing, which has an annual cost reduction of 6.6 million. Training agency staff on NSIS methods, which has an annual cost of about 68 thousand and converting food inspectors into consumer safety inspectors, which has an annualized cost of approximate 229,000.

Few changes would occur at the 22 large and 13 small high volume establishments expected to convert to NSIS.

Next slide please. This slide has a snapshot of the cost and benefit associated with the proposed rule. I think the main point is that under the Executive Order 12866 cost-benefit analysis processes, which includes health benefits, this rule has annual cost savings of 31.77 million dollars a year.

Next slide please. Our analysis also took into consideration Executive Order 13771, which is the reducing regulation and controlling regulatory cost. Consistent with those Executive Order, we have estimated that proposed rule would yield cost savings of approximate 24 million dollars, not including health benefits. Therefore, if finalized as proposed. This rule is expected to be an Executive Order 13771 deregulatory action.

Melissa Hammar: The next slide. This is just a reminder that comments may be submitted on the rule until May 2nd. These are just instructions on how you can submit comments. I think we're going to open it up for questions now.

Rita, ATT: Ladies and gentlemen as we move to Q&A, please feel free to place yourself into the questions queue by pressing #2 on your telephone keypad. You will hear a notification when your line is unmuted, at that time, please then state your name and question. To submit a written question, use the chat panel on the right-hand side of your screen to all panelists from the send to drop down menu.

Cody Kahlig: Okay guys, so, we just got our first question. The establishment can still slow the line as well, correct? Slide 18 sounds like the establishment no longer has this control. Could we go to slide 18 please?

Melissa Hammar: The establishment can still slow the line. They still maintain control over that.

Cody Kahlig: Okay. Is the time increase in humane handling or HATS verification by SSIS personnel proportional to the increase volume of animals being slaughtered since there are more animals being slaughtered in that time. Is the increase in HATS time sufficient to keep up with that volume?

Melissa Hammar: So we compared the five HIMP plan to 21 other non-HIMP plans that are slaughtering the same volume and we found that even at the same volume, we're performing more offline inspection tasks under HIMP**.**

Cody Kahlig: Okay. Is the restriction on plant employees stopping or slowing the line a regulatory requirement or an industry decision?

Melissa Hammar: Again, establishments still have control over their lines and they can slow their lines or stop their lines. Slide 18 was just what we'll do if we find issues. What our authority is and it's the same authority we have under traditional but it just seems like we've been getting questions about when we can slow and stop the line so we wanted to be very clear. If we see issues, this is when we will slow or stop the line.

Cody Kahlig: What is the reasoning to revoke maximum lines speeds?

Melissa Hammar: Right now the task or maximum lines, these are based on old work measurement. It involves how long it took an inspector to walk from one inspection station to another and nowadays it is everything is... most establishments are very automated and it just an archaic standard.

Cody Kahlig: How many tests can be conducted for *Salmonella*, *Campylobacter*, STEC, and *Toxoplasma gondii* in each in shift?

Rachel Edelstein: I assume that this question is asking about FSIS testing and right now there is an exploratory sampling program going on for pork parts and comminuted pork. It does include *Salmonella*, *Campylobacter* and STEC for slaughter establishments. It does not include the *Toxoplasma gondii* and it's not structured on a per shift basis. It's more based on what products they're producing and volumes. It's an exploratory program. It's not related to this rule at all. I think Melissa pointed out, we did propose to remove the *Salmonella* standards for carcasses... so, we may use this data to propose new standards for *Salmonella*, but it's just that we have not yet come to a conclusion on that.

Melissa Hammar: Next mention one more thing about line speeds. So, under the HIMP report, we found that the HIMP establishments were running approximately this same as traditional. So, we've been under this proposal, we don't expect a huge change in line speeds. We're just removing any obstacles to innovate them.

Cody Kahlig: Okay, first slide, 34. Let's go to slide 34. What if the establishment is a hot bone operation and has no post chill carcass for which to sample.

Rachel Edelstein: This is a good question and this is an issue that we did not address in the rule or in the compliance guidelines. So, we'll make a note of it. But if we encourage you to submit that as a comment. I think we'd like to be able to address that in the final.

Cody Kahlig: Okay. If facilities are not required to collect samples for specific organism, *E. coli* and *Salmonella*, how will FSIS verify whether each individual facility is

performing similar to, better than, or worse than its peers with respect to contamination?

Rachel Edelstein: This is very consistent with what we proposed and went final with, with the New Poultry Inspection System. It's up to the establishment; they have to have a plan that will address fecal and microbial contamination throughout the system. So, they need to come up in their plan...at a minimum, their plan has to have sampling for microorganisms. So, they're required to develop a plan that they can show will address microorganisms and fecal throughout the system. FSIS inspectors will verify that they do have a written program and verify that the plant can support their program and verify that their implementing their program as written.

Cody Kahlig: Alright. How are the health benefits measured, how many illnesses, death, and long-term health outcomes are expected to be reduced?

Michelle Catlin: Hi, this is Michelle Catlin, the Director of the Risk Assessment and Analytics Staff. In the risk assessment, we use a prevalence-based methods, which looks at the illnesses using CDC data and we also link that up to our own sampling results to see what the decreased numbers of illnesses are. As Lindsey said in the presentation, the most likely decrease for the scenario that looks similar to the HIMP establishment and what's being proposed in the New Swine Inspection System is a decrease of 2,533 illnesses and that's a decrease from about 69,000 illnesses per year.

Cody Kahlig: Will there be a lead slaughter CSI-9 in NSIS?

Rachel Edelstein: I'm sorry, that's a detail I don't think we can answer right now.

Cody Kahlig: Okay. Will these slides be available to print for distribution to online inspectors?

Melissa Hammar: Yes, this whole presentation is being recorded and we're going to post it on our website, yes.

Cody Kahlig: Okay. So, can you clarify what all plants are now required to do versus voluntary plants and why mandatory plant costs appear to be more?

Rachel Edelstein: I think the first part of the question of what all plants are required to do…

Melissa Hammar: We're proposing a voluntary inspection program and then we're proposing new sampling requirements for all establishments. So, the voluntary costs are... those are again voluntary and that's... Andrew jump in….but it's like training, and…

Andrew Pugliesi: Sure. The voluntary costs come to about 17 million dollars a year whereas mandatory cost come in at about $820,000 a year. Mandatory costs are much lower than the voluntary cost.

Melissa Hammar: Voluntary costs again are like training and hiring new sorters.

Andrew Pugliesi: Voluntary cost are associated with labor needs.

Melissa Hammar: Yeah. It is all, again voluntary if you don't choose to do NSIS, you can continue to operate under traditional.

Cody Kahlig: In the graphic provided for post-mortem inspection staffing, there was one PHV, two offline inspection personnel and three line inspectors. In the large volume slaughter processing establishment, will there be a separate offline personnel for the processing side, example three offline personnel?

Melissa Hammar: We didn't address processing, so that infographic is just for slaughter. So, it won't change the staffing. This rule does not change staffing for processing.

Cody Kahlig: What is the definition of maintaining process control and how can that not include adequate handling and stunning of animals?

Rachel Edelstein: When we talk about process control, we're talking about maintaining process control for microbials like *Salmonella* and food safety issues.

Melissa Hammar: It's a different statutory authority, too... when we talk about maintaining process control we're talking about meeting food safety and non-food safety defects. We are still verifying the Humane Methods of Slaughter Act though. So, we will still be... and as I mentioned before, we actually conduct more offline verification tasks for humane handling.

Cody Kahlig: How far in the process does the pre-operational swabbing expectation extend? Is it intended just for the conversion floor and those lines where the carcass exposed pre-chill or are the fabrication both post-chill and for the processing areas included?

Melanie Abley: All right, this is Melanie Abley, and initially we were just expecting this for the slaughter itself, the slaughter floor. However, since this is a new requirement that we're proposing. We would welcome comments on this, so we can further flesh this out and we'll address this in the final rule.

Cody Kahlig: Yes, again the presentation will be available for distribution. Does the total number of inspectors per plant stay the same?

Andrew Pugliese: No, the total of inspectors per plant does change or for establishment that wanting to participate in NSIS. The number of inspectors per establishment decreases as establishments participate in NSIS.

Cody Kahlig: Will very small establishment be required to do pre-op swabbing for process control?

Melanie Abley: As provided in in this compliance guideline that's included on the web with the proposed rule. Yes. That would be a requirement for all establishments, even small and very small.

Cody Kahlig: This is a follow-up question. Given that not all facilities will be required to test for the same organisms, is it accurate to say that FSIS will not necessarily be able to verify whether an individual establishment is performing similar to, better than, or worse than its peers on microbial standards?

Rachel Edelstein: Again, when the establishment is doing its own testing that's data that FSIS is collecting. If FSIS, I mentioned the exploratory sampling that we're doing for - in pork establishments now. If we move forward with new performance standards, we would use FSIS testing to be able to assess establishments and, you know, compare.

Cody Kahlig: Why is the FSIS risk assessment based on *Salmonella* testing of whole carcasses? Didn't the agency discontinue whole carcasses testing because of the number of positive samples was insignificant?

Michelle Catlin: Yes, we did use it on carcasses, the data from the whole carcasses, those were the data that were available for us to use in the risk assessment and even though the number overall was very low, when we pooled all the data together and looked at all the data from all the establishments, there was more than adequate data to be able to look at relationships between our activities and the facilities and the problems in each individual establishment.

Lindsey Ward: Also, the relationship between contamination prevalence, on whole carcasses and human illnesses has been published in the peer-reviewed literature and so that is our kind of scientifically supportable relationship.

Cody Kahlig: When establishments sort, reject, to go to another location; generally, they would need permission to transport from a slaughter facility due to disease concerns. How will this be handled?

Melissa Hammar: It will be handled the same way it is currently under traditional inspection.

Cody Kahlig: All right.

Melissa Hammar: I just realized…I realize want to emphasize that…the ante-mortem inspection is very, very similar between traditional inspection, HIMP, and what we're proposing under NSIS. The main difference is that they don't do a very good job sorting. We'll give them an NR. The establishments are more responsible for detecting food safety defects and all of the sorting it's pretty much the same.

Cody Kahlig: Already, under NSIS who has the responsibility to check the sensibility post-stunning?

Melissa Hammar: It's the same as it would be under traditional.

Cody Kahlig: Yeah, why is pre-operational sanitation inspection and sampling being added to the swine inspection rule?

Melissa Hammar: Okay, we explained in the proposed rule that we had an outbreak and we were proposing this because of that. Again, we're asking for comments, so please submit comments on that proposed sampling.

Cody Kahlig: Okay. If *Salmonella* detection rates are similar between HIMP and similar non-HIMP plants then why should we adopt this new system?

Rachel Edelstein: It's really up to the establishment to decide whether to go into the new system. I mean, the establishment is likely to choose the new system if they see that there is some benefits to them - to operating under the new configurations and to having more control over the sorting and more control over the lines.

Cody Kahlig: Was an intended goal of the proposal to increase humane slaughter oversight or focus on food safety and microorganisms?

Rachel Edelstein: I would say the main overall we wanted to modernize the inspection system and make better use of agency resources and I think that any benefit that we can make to humane slaughter and micro, we would want to achieve those also.

Melissa Hammar: Right, we inspect for both food safety and humane handling. So, the purpose of the rule and the highlight was just to make sure that we're inspecting as effectively and as efficiently as we can.

Cody Kahlig: How is process control the find in terms of micro-biological criteria?

Rachel Edelstein: We don't have a specific definition. If there are...once we set performance standards for different products, part of how we would look at is an establishment maintaining process control, we would look at are they meeting the performance standards that we've set, or other guidance.

Cody Kahlig: Has the grade level been determined for the new positions?

Male Speaker: The grade level has been determined. I would refer you to the proposed rule for details.

Cody Kahlig: Follow-up under NSIS, who has responsibility to ensure proper stunning?

Melissa Hammar: Again, the same as traditional FSIS PHV is the one who ensures humane handling and does all of the condemnations, the PHV still has the same authority under HIMP and under proposed NSIS that they have under traditional.

Cody Kahlig: The proposed rules state that establishments may substitute alternative sampling frequencies if they are able to provide definitive improvement in monitoring process control than prescribed frequency. Could we get an example of what definitive improvement might look like?

Rachel Edelstein: As we were talking about the establishments would have to develop a sampling plan and be able to support their sampling plan. In the case where they want to show a different frequency, we would need to see their results and

we would need to be able to see some improvement in their test results. I don't think that we have any examples in the compliance guideline or in the rule. So, this would be a good one and we'll make a note of it but this would be a good one to submit a comment on.

Cody Kahlig: Is all plants require to do part of the new rule? There is confusion that NSIS is voluntary but some of NSIS is mandatory for all establishments. My plant is part of 8%, of the 8% they slaughter one day a week. Are they to sample each week all year or just 13 weeks that are required?

Melissa Hammar: If you're very small, you would just do the 13 weeks that are required. So, there is the new inspection system, which is the new slaughter system, which is voluntary. Then completely other part of the proposal is the new sampling requirement for all establishments. But again, if your plant is a small plant, then yes, you would just do 13 weeks anyway.

Cody Kahlig: If the number of inspectors decreases for plants participating in NSIS, how is the decrease decided? Currently, there are seven per each HIMP plant**,** correct? So, how many will there be for NSIS?

Andrew Pugliese: Again, this is a pretty well-detailed in this proposal rule. As I understand it, right now, slaughter lines has up to seven online inspectors and that's under traditional. That's going to be reduced down to, more likely than not, three, one with the head, viscera, and carcass and final. Also under traditional, there is typically one offline inspector under NSIS, there'll be two offline inspectors. But again, please refer... this is detailed and proposed rule where I would suggest you go and find it... Also, we welcome comments.

Lindsey Ward: Could you return to slide 42 for the information about how to submit a comment? For the last slide. Sorry, 42 is wrong.

Rita, ATT: Can take verbal questions?

Selena Kremer: Yes, please go ahead with verbal questions.

Cody Kahlig: We're going to take a short break and then we will open the lines up for verbal questions. Okay, guys so, we actually have one more question and then we're going to open up the phone lines, or actually I think there's two, let me...

Melissa Hammar: The question was... that this presentation is very focused on market hogs and we were wondering how it applies to other establishments. So, we did say if you're interested in participating in NSIS, and you slaughter animals other than market hogs, you can apply for a waiver. Then for the mandatory proposed requirements that applies to offline, whether it's market hog or any other class of hogs.

Cody Kahlig: Okay, we have one more. What is considered food contact surface throughout the process? Is food contact surface considered from corrals all the way through to knock box and to scalder and to final rail to cooler?

Melanie Abley: As mentioned previously in the compliance slide that's available, there are examples of what we were proposing for food contact purposes and so you can go there and see what our thinking was. However, as we said before please submit comments so we can have the comments available for the final rule.

Cody Kahlig: Okay, at this time we are ready to answer any comments over the phone and we're ready to open the phone lines.

Rita, ATT: We will move to the first caller and just a reminder to the rest of the audience, that's #2 on your telephone keypad if you like to enter the verbal queue. Caller your name has been unmuted, please state your name and go ahead.

Tony Corbo: Tony Corbo from Food and Water Watch. In September of 2017 the agency granted us *Salmonella* Initiative Program waiver to a brand-new state of the art hog slaughter facility in Coldwater Michigan, 791C. In December, the plant implemented this new system where the number of online inspectors was reduced and that could increase its line speed. Approximately, two weeks after that happened, the plant was gradually increasing its line speed and then it reached the line speed at which it claimed it lost process control. We received the Freedom of Information Act, the documents from a FOIA we filed on October that indicates that the plant did lose process control and the line speed was redacted. Can you please elaborate what specifically the plant encountered, what it increased the line speed and lost process control and what was the line speed?

Rachel Edelstein: I'm sorry, this is Rachel Edelstein. We don't have that information here.

Tony Corbo: Well, Rachel you know, you've been dancing around the process control question all during this webinar and I want to know specifically because this plant is obviously modeled after this proposed rule and you should have an answer to it.

Rachel Edelstein: Yeah, I don't have the specifics here, sorry.

Rita, ATT: Moving to the next question in the queue. Caller your line has been unmuted, please state name and go ahead.

Sarah Sorscher: Hi, this is Sarah Sorscher from CSPI. I had a question about the performance standard. The proposed rules state that you stop testing in 2011 after finding that contamination rates were low in whole hogs and you have these new results from 2016/17, which appeared to test different parts at a different stage in the process. Do you have any data to track what happened, whether contamination rates went up or down with whole hogs after you stopped implementing, sub-testing for that performance standard or any other measure to see what impact it might have had on contamination rates?

Rachel Edelstein: We don't have... once we've stopped testing for the whole hogs, we did a baseline and then we started the exploratory testing. So, we have... and all of that data is posted.

Michelle Catlin: Yeah, the baseline data is available that was last around the time we were still doing the testing for the carcasses and we have a previous carcass testing but we do not have more recent data on whole coccus testing just on parts.

Sarah Sorscher: My question is, do you have comparable data from what you did in 2011 and what you've been doing since then? Is the data comparable or can they not be compared to see if rates have gone up or down?

Rachel Edelstein: I think it's different products.

Michelle Catlin: Yeah.

Sarah Sorscher: You can't track and say after we stopped testing there was no negative impact on contamination rates from that.

Michelle Catlin: We do not have those data, no.

Rita, ATT: Moving to our next question. Caller your line has been unmuted, please state your name and go ahead.

Thomas Gremillion: Hi, this is Thomas Gremillion from Consumer Federation of America. I guess going back to Tony Corbo's question about process control. I'm just really confused about what process control is and how that how loss of process control will be identified in... You mentioned performance standards, telling us performance standards and in response to an earlier question I had. My understanding is the only performance standard was for *Salmonella* for whole carcasses and that was discontinued. So, testing for that was discontinued. Can you ever give us some examples of how FSIS would find that a plant has lost process control on the basis of microbiological criteria?

Rachel Edelstein: We do have some examples of that in the microbiology sampling programs guideline that we posted with the rule.

Thomas Gremillion: I'm sorry, I don't have that in front of me now. They're not…Are there are other performance standards that I'm missing? That wouldn't be...

Rachel Edelstein: Other than the codified standards for hog carcasses, we don't have additional performance standards for pork products at this time. Like I said, we're doing the exploratory program. We're going to analyze that data and then we'll make a determination whether to propose new standards.

Thomas Gremillion: So violating the performance standards, unless there's some new standard created won't be the way in which you define process control violation because there's no performance standard to violate. So, and I'm sorry I don't have the guideline you're talking about. I don't have that available right now. So, what

would happen to trigger FSIS personnel to say, this is the loss of process control?

Rachel Edelstein: If we saw…if they're doing their own testing and we saw that their results... as they have set, we have examples where they have set and it's in the guidelines, they set a maximum acceptable level of an organism and we would probably issue instructions like what we issue for poultry. If the establishment is findings it's results consistently over the acceptable maximum level and not taking any action.

Thomas Gremillion: So, you're asking them to set their own performance standard?

Rachel Edelstein: They have to set, just like poultry, they have to set up their own testing program.

Rita, ATT: Please to our next question, caller your line has been unmuted, please state your name and go ahead.

Suzanne McMilan: Hi, it's Suzanne McMilan with the ASPCA, I'm wondering whether FSIS tracks the number of swine who are condemned following entering the scalder before proper slaughter has happened. So, in other words they would be essentially drowning in the scald water and they would be that dirty water in their lungs. Is that being, are those numbers being tracked and are they public?

Rachel Edelstein: Kevin or Tom online, do you know?

Tom Vermeersch: The way FSIS verifies that it's just part of the humane slaughter verifications that we do and the fact that we are observing animals for return to consciousness after the bleeding process has begun. What the caller mentioned is, I'm going to say, unheard of in swine establishments, because it just doesn't happen. The establishment has people that verify the animals are not returning to consciousness and FSIS also inspects for that over the course of doing their humane slaughter verifications.

Kevin Gillespie: If they did happen, that would be an egregious violation.

Tom Vermeersch: Absolutely.

Rita, ATT: At this time there are no further questions in the queue.

Selena Kremer: I'm sorry, Rita**,** did you say there are none?

Rita: There are no further questions.

Rachel Edelstein: I'm going to just clarify one issue that we thought might be a good idea to clarify here. When FSIS has established performance standards for certain products and we have set those based on FSIS test results, what we're requiring for all the hog slaughter establishments is that they have to do their own testing to assess that they have effectively addressed fecal and microbial contamination throughout the system. So, that is different than our performance standards.

They would be required to set up the measures that would work for them and would show them that they're achieving the level of process control that they need to achieve. Then inspectors will verify that they have the program, it's written, it's documented, they can support it, and they're implementing their program.

Rachel Edelstein: Oh, we do not intend to do a public meeting on this proposed rule.

Cody Kahlig: Okay, are there any more questions?

Rita, ATT: No new questions have come through.

Cody Kahlig: Okay, we thank you guys for joining us on our webinar and hope you have a great day.

Rita, ATT: Thank you for joining today's conference, the call has now concluded and you may disconnect.

[END OF TRANSCRIPT]