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Swine Modernization Webinar: April 16, 2018, 2-4 p.m. ET

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Rita ATT: Welcome and thank you for joining today's conference, Swine modernization. Please note that all participant 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 on the Sent To dropdown menu. If you require technical assistance, send a note to the event producer. With that, I'll turn the call over to Dr. Selena Kremer, please go ahead.

Selena Kremer: Thank you and good afternoon. Thanks for dialing in to today's Webinar on FSIS' Proposal to modernize swine inspection. We want to use this opportunity to give an overview of the proposed rule that FSIS proposed on January 19th. This is an opportunity for you to ask clarifying questions on the proposed rule. We will not be accepting comments on the proposed rule on this webinar. However, we encourage you to submit comments on regulations.gov. Instructions for that will be provided throughout the presentation. Throughout this webinar, we will have several subject matter experts speak on specific parts of the proposed rule in their area of expertise. I will introduce each of them as we move through the webinar. During the webinar, we will pause after each section for your questions.

Please note that this webinar is not providing new information outside of what is already in the proposed rule. Because FSIS does not have additional information beyond what has already been proposed the agency is not holding a public meeting.

Finally, before we start the webinar, I want to let you know that this webinar is being recorded and we will provide the transcript and the presentation on the FSIS website. Let's get started with the Webinar. It is my pleasure to introduce Melissa Hammar. Melissa is the Deputy Director of the Office of Policy and Program Development Issuances Staff. Melissa?

Melissa Hammar: Thank you, Selena. As Selena mentioned, my name is Melissa Hammar. I'm with the Office of Policy and Program Development. I'd like to start off today with an overview of this webinar. We'll start with an overview of the proposed rule, a brief explanation of the traditional inspection under existing regulation, the need for modernization. Our experience under the hazard analysis and critical control point-based inspection models project, our analysis

with that project, and we'll break for questions. Then Lindsay Ward-Gokhale from our Risk Assessment and Analytics staff will walk through the risk assessment.

I will go through the proposed new swine slaughtering inspection system, the proposed requirements for all of swine slaughter establishment and again, we'll break for questions. Then finally, Andrew Pugliese will walk through the economic assessment. Let's get started by turning to slide three with an overview of the proposed rule.

As you can see there are two components to the proposed rule. We're proposing a new voluntary inspections system from market hog slaughter establishment. It's called the New Swine Slaughter Inspection System. The system is informed by the agency's experiences under the Hazard Analysis and Critical Control Points-based Inspection Models Project. Otherwise known as the HIMP project. Market hogs slaughter establishments that do not choose to operate under the new Swine Inspection System may continue to operate under their existing inspection system.

Just a quick clarification, we published the proposed rule on February 1, 2018 and the comment period ends on May the 2nd. The proposed rule is posted on our website. The second component of the proposed rule is, we're proposing several changes to the regulations that would affect all establishments that slaughter any size, age or class of swine. To understand why we're proposing these changes, let's go over how inspection is connected on under our existing regulations. Let's move to slide 4. On traditional inspection, market hog establishments have the option to do some sorting activities before FSIS ante-mortem inspection. Most market hog establishment use these voluntary segregation procedures.

Before FSIS inspection, they segregate healthy animals from animals that may be showing signs of disease conditions. However, under traditional inspection, establishment personnel conduct no post-mortem sorting activity. FSIS inspectors check each carcass for food safety and non-food safety defects and direct plant employees to take corrective action. FSIS public health veterinarians (PHV) condemns carcasses with animal diseases and plant employees dispose of condemned carcasses. FSIS inspectors spend too much time inspecting for non-food safety defects such as bruises that are more related to the marketability of the product.

To help understand how we conduct ante-mortem inspection under traditional inspection, let's turn to slide four. We have a diagram of voluntary segregation procedures and FSIS ante-mortem inspection.

So, market hog establishment personnel, segregating animals that appear to be normal and healthy from abnormal or unhealthy animals that appear to have condemnable conditions. These animals that appear to have condemnable conditions are moved into the U.S. Suspect pen where they examine them. The FSIS PHV examines all market hogs in the U.S. Suspect pen. The PHV then classifies the market hog as passed for slaughter or condemned.

FSIS requires establishments that sort under the voluntary segregation procedures to document their procedures in their HACCP plan or prerequisite program. FSIS examines all animal found by the establishment to be normal at rest in 5 to 10% of those animals in motion. If any animals exhibit signs of condemnable conditions, FSIS inspectors' direct establishment employees to move those animals to the U.S. Suspect pen for final disposition by the FSIS PHV. FSIS inspectors observe establishment employees performing their segregation procedures at least once per month.

Now for a more in-depth view of post-mortem inspection procedures under traditional inspection, let's turn to slide six. This is a diagram of what a large high-volume establishment would look like under traditional inspection, with up to seven online inspectors, one offline inspector and one public health veterinarian. The FSIS inspectors conducting online activities spend most of their time 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 establishments are meeting their HACCP critical limits and verifying whether their sanitation SOPs are effective. The FSIS PHV oversees the whole process.

Let's talk about how FSIS records this disposition data. Let's turn to slide seven. Under the existing regulations, only FSIS inspectors may direct the application and removal of the U.S. condemn tags from animals and carcasses condemned by FSIS inspectors on ante-mortem and post-mortem inspection. FSIS inspectors input the number on each U.S. condemned tag into Public Health Information System (PHIS).

Under the existing regulations, most U.S. condemned tags are applied during ante-mortem inspections to animals that arrive dead. The health FSIS inspectors are responsible for removing all of the U.S. condemned tags and documenting each U.S. condemned tags in PHIS. It takes inspectors more time to complete ante-mortem and post-mortem inspections, but it would if establishment sorted and remove these animals before FSIS inspection and maintained

records that could be verified by FSIS, as appropriate, and reported their daily total to FSIS inspectors.

Now that we've gone over the current regulatory requirements for inspection, let's talk about why we want to modernize. Let's move to slide eight. The traditional inspection was developed before HACCP regulations and before the agency began targeting its resources to address public health risks associated with foodborne pathogens. In addition, there have been advances in the animal science and market hog production systems. These animals are a lot healthier than they were back in 1906 when traditional inspection started. Under traditional inspections, inspectors are required to spend a large amount of time inspecting for quality-related defects rather than verifying food safety related process controls in effectiveness of the HACCP system. In addition, traditional inspection limits line speeds and restrict the establishment's ability to reconfigure and consolidate their lines.

Let's move to slide nine. FSIS has been experimenting with new ways of inspecting since FSIS published the Hazard Analysis rule. Shortly after we published the Hazard Analysis and Critical Control Point Law, we began experimenting with the Hazard Analysis and Critical Control Point-based Inspection Model Project or the HIMP. The FSIS initiated the HIMP study in 20 young chickens, five young turkeys and five market hog establishments on a waiver basis. Sorting activities shifted from FSIS inspectors to establishment personnel. Before FSIS ante-mortem inspection, establishment employees sort animals. Before FSIS post-mortem inspection, establishment employees sort carcasses and parts and trim dressing defects and contamination. Establishment employees sort and FSIS inspectors inspect. These sorting activities are very different than inspection activities. FSIS inspectors still conduct a 100% ante-mortem and 100% post-mortem inspection.

Let's move to slide ten. Before the implementation of the HIMP project an independent contracting firm collected baseline organoleptic and microbiological data in five market hog slaughter establishments that volunteered to participate in the HIMP program. These better reflect the performance of the establishment under traditional instruction and provided the basis to establish HIMP performance standards for food safety defects and non-food safety, other consumer protection (OCP) defects. This chart shows the three Food Safety (FS) performance standards. FS1, addressing infectious conditions, FS2 addressing contamination from fecal ingest by milk and FS3 addresses certain conditions identified at ante-mortem, such as neurological conditions. The FSIS has

established a zero tolerance policy for food safety conditions. FSIS conducts 100% inspection for FS conditions.

Let's turn to the next slide and look at OCP performance standards. FSIS establish the performance standards for non-food safety, OCP defects based on the performance level of the establishment representing the 75th percentile for each category of OCP defects. FSIS established three categories of OCP performance standards for various types of trim and dressing defects that primarily affects the quality of products. The OCP1 addresses carcass pathology defects, OCP2 addresses visceral pathology defects and OCP3 addresses miscellaneous defects such as bile, bruises and skin lesions. To participate in the HIMP program, establishments operating had to maintain process control plans to meet performance standards for food safety and non-food safety OCP defects. The FSIS conducts at least 24 carcass checks for non-food safety defects. FSIS tracks these defects over time to verify that establishments are meeting the OCP performance standards.

Let's turn to the next slide to see how FSIS tracks performance. FSIS 24 carcass checks for non-food safety defects are used to verify that the establishment complies with OCP performance standards and FSIS zero tolerance for fecal, milk, ingesta contamination at the FSIS final rail. The 24 carcass checks are split into randomly scheduled subsets. Three sets of eight, six sets of four. A number of OCP defects found by FSIS for each shift are compared to the defect standards listed in table one. IPP (inspection program personnel) record whether the establishment passed or failed that check for each OCP category. Table two shows the maximum number of days for each OCP category that the establishment is allowed to exceed FSIS OCP performance standards and when IPP document noncompliance for not meeting the HIMP and OCP performance standard. If online inspectors have concerns about missed OCP defects, they have to notify the FSIS PHV. The FSIS PHV will determine whether to assign additional unscheduled carcass checks. The table one shows how the performance standards change depending on the number of carcasses checks per shift. Data from the HIMP establishments show a history of excellent establishment process controls for OCP conditions.

Let's turn to the next slide and see how sorting an ante-mortem looks under the HIMP project. As you can see from this table, it's very similar to the voluntary segregation procedures described that we went over before for traditional inspection. Like voluntary segregation, establishments sort healthy animals from unhealthy animals or animals that appear to have disease conditions. Under

HIMP, animals that appear to have disease conditions are moved into the U.S. Suspect pen where they are subject to additional FSIS inspection. FSIS inspectors examine a 100% of the animals in the U.S. Suspect pen. The FSIS Public Health Veterinarian determines whether those animals should be sent to the U.S. Suspect pen or if they pass inspection. A big difference between HIMP sorting and sorting under traditional inspection is that there is zero tolerance for food safety conditions. If an establishment does not properly sort for food safety conditions, the FSIS Public Health Veterinarian may issue a noncompliance record (NR).

Let's move to slide 14 and see what post-mortem inspection looks like under HIMP. As you can see under HIMP, in most establishments, there is one FSIS online inspector at the head station, one online inspector at the viscera inspection station and one at the carcass inspection station. FSIS has assigned two offline inspectors and one public health veterinarian, but because establishment employees are required to sort carcasses and parts and identify defects before FSIS inspection fewer adulterated carcasses and parts are presented for FSIS inspection. As a result, FSIS can assign fewer inspectors to online inspection, freeing up agency resources to conduct more offline activities such as HACCP tasks or Sanitation SOP verification procedures. FSIS can conduct more offline humane handling verifications, as well. Again, the FSIS PHV oversees the whole process. The vast majority of market hogs are healthy animals, plant sorters are to identify any abnormalities and direct carcasses and parts offline for further sorting by the establishment sorter.

For example, if the sorter determines the hog has signs of septicemia, they send the carcass and parts to inedible rendering and establishment documents the move and their sorting records. If the sorter determines the carcass does not have condemnable conditions, the carcasses are trimmed and re-presented to the FSIS online inspector. The PHV through direct observations and record reviews, verifies establishment sorting procedures are effective and that sorters are removing all food safety and condemnable OCP conditions. If the establishment online sorter does not identify a carcass with a condemnable condition, the online FSIS inspector retains the carcass for PHV disposition. The PHV would document an NR.

Okay, let's move to slide 15. On slide 15, you can see an example of how defects are marked under the HIMP inspection system. Defects are marked with ink, and in some cases, the carcasses are tattooed so that establishments can easily identify defects. If we move to

slide 16, we can talk about how FSIS maintains disposition data under HIMP. Under HIMP, FSIS inspectors document in PHIS the total number of animals that the establishment employees have sorted and removed per day and any animals that may have been missed by the plants orders, but identified and condemned by FSIS. Because we're only entering the total numbers, FSIS inspectors are able to save a lot of time and they're able to use that additional time to conduct offline activities.

Let’s move to slide 17. Who can stop or slow the line under HIMP? The establishment can always slow or stop their lines. An online and offline FSIS inspector and public health veterinarian may also stop the line. FSIS would stop the line if inspectors find insanitary conditions, contaminated organs or parts that would create insanitary conditions or would interfere with inspection. They may also stop the line when online IPP find a zero tolerance defect at the final rail or when there is an immediate personnel safety concern. This is all consistent with current regulation.

Let’s turn to the next slide and see when we would slow the line. Again, consistent with current regulations, only the PHV would slow the line. The PHV would slow the line if there are excessive disease or OCP defects. There are deficiencies in carcass presentation or preparation that can affect FSIS’ ability to adequately inspect. Examples of that would be missing organs apart or excessive contamination.

Let's turn to the next slide and talk about humane handling. The FSIS or HIMP does not change how FSIS verifies and enforces the Humane Methods of Slaughter Act (HMSA). FSIS inspectors perform the same humane handling verification tasks. FSIS inspectors verify that establishments comply with the HMSA they're performing humane activities tracking system tasks that are divided into the nine categories below. The HATS task provides FSIS with data on the time that FSIS inspectors spend verifying the following in this list.

Turning to the next page. The Hog HIMP report did not address compliance with the HMSA but FSIS reviewed HATS task data in PHIS from January 2013 through September 2015 and compared the number of offline humane handling activities performed in the five HIMP market hog establishment and the same 21 comparable large non-HIMP market hog establishments that FSIS used in the HIMP report. The agency found that FSIS inspectors spent more time verifying humane handling tasks in the HIMP establishments than they did on the non-HIMP establishments. These data demonstrate that HIMP establishes may have higher compliance with the humane

handling regulation than non-HIMP establishments and that increased offline inspection may improve compliance with the Humane Methods of Slaughter Act.

In 2004, FSIS completed the evaluation of our market hog HIMP project. We turn to slide 21, you can see the key questions that we asked in our evaluation where you looked that our HIMP market hog establishment, preventing contamination as well as non-HIMP market hog establishments. Our HIMP market hog establishments meeting food safety and other consumer protection performance standards. Key components of the assessment. We looked at comparable non-HIMP market hog establishments and we looked at multiple FSIS data sources including inspection data in a microbiological and residue testing data in our OCP record.

We turn on to the next slide. We'll look at the conclusions of the HIMP report. Data indicated generally comparable performance between HIMP and similar non-HIMP establishments. There were HIMP report found that the HIMP system is at least as safe and effective as traditional inspection. Now we'll open it up to see if there is any questions on what we've gone over so far.

Selena Kremer: Rita, before we open the lines, I just wanted to clarify for everyone on the call, we are recording this webinar. The transcripts and the presentation will be on the FSIS website. Then also we've got a question about the March 22nd webinar that we did on swine modernization. Yes, I just wanted to confirm that that information is posted on FSIS' website as well. Rita, we can go ahead and open the lines to take questions now.

Rita ATT: Ladies and gentlemen, as we move to Q&A, please feel free to place yourself into the question queue by pressing pound 2 on your telephone key pad. You will hear 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 choose All Panelists from the Send To drop down menu.

Selena Kremer: Thanks, Rita. And while folks are dialing in we have our first question on the chat feature.

Cody Kahlig: The first question is how will downer animals be classified and sorted during ante-mortem inspection?

Melissa Hammar: These animals must be sorted into the U.S. Suspect pen where they will be inspected by the US or the FSIS Public Health Veterinarian.

Cody Kahlig: The next question is, is the condemnation information that gets entered into the PHIS database, is it available publicly?

Rachel Edelstein: I guess I could start with by just pointing out that the Hog HIMP report that Melissa was just discussing includes information about condemnation rates for Hog HIMP establishments and other similar hog slaughter establishments. More generally, it's not public on an ongoing basis.

Tom Vermeersch: This is Tom Vermeersch. The information that FSIS gathers on condemnation are shared with the National Agricultural Statistics Service (NASS) and the USDA Animal Plant Health Inspection Service (APHIS). Both of those agencies within USDA use that data for tracking and monitoring trends in national disease programs, and you'd have to check with those agencies to find out what their information is, how they share that information with the public.

Selena Kremer: Thank you. Rita, did we have any questions on the phone?

Rita ATT: There are no verbal questions at this time, but just a reminder, pressing pound 2 will enter you into the question queue. We actually did just receive a verbal question. Caller, your line is unmuted. Please state your name and go ahead.

Tanya Roberts: Is this on the phone? This is Tanya Roberts for CFI. I guess I'm surprised that you talk about the importance of seeing bruises and how the inspectors are spending most of their time on bruises. This is so reminiscent of what happened. Hello?

Selena Kremer: Yes, we can hear you, please continue.

Tanya Roberts: What happened when I was first asked to review a benefit cost analysis of inspection activities to reduce the number of activities that related to chickens. Again, the statement was made that the bruises and broken wings are primarily what inspectors were inspecting for when that really wasn't true. Again, fecal contamination is a huge problem. It doesn't necessarily cause disease in the hogs, but it can cause disease in humans. This whole presentation is rather strange to me.

Rachel Edelstein: Okay, we'd certainly welcome... I mean, that sounds like we'd welcome written comments on that issue.

Selena Kremer: Please go to regulations.gov to provide written comments on the proposed rule, thank you. Rita, did we have any other verbal questions?

Rita ATT: There are no further verbal questions at this time.

Selena Kremer: Okay, let's take our next written question.

Cody Kahlig: The next written question is why did FSIS only use the routine sampling results from 16 of the approximately a 150 non-HIMP plants from which data was collected. How did FSIS ensure that these data were representative of non-HIMP plants, table 1, page 21 of the risk assessment?

Lindsay Ward-Gokhale: Yes, hi my name is Lindsay Ward-Gokhale. I am with the Risk Assessment and Analytics staff. The table that you speak of table 1, describes the HACCP data set used in the risk assessment, not a sample. As you'll see in the far-right column, it says a sum 16 plus 143 that totals all the establishments that are used in that particular context. The data for that table are broken down further in the appendix table A2, which can be found on page 79 for more details.

Selena Kremer: Thank you, Lindsay.

Selena Kremer: Okay, we'll go to our next written question.

Cody Kahlig: What are the duties of the plant employee carcass inspectors? Where is the FSIS inspector online there in the process? Is an online inspector overseeing these carcass inspectors?

Melissa Hammar: First, I'd like to clarify that there are no employee inspectors. FSIS is not privatizing inspection. FSIS and only FSIS can conduct inspection. There are employee sorters that look at viscera and carcass before FSIS conducts their inspection. These sorters look for food safety defects or other consumer protection defects and either identify the defects for removal. They just identify the defects for removal. Then FSIS, looks at the defects and determine whether the carcass may pass or if it needs to be condemned. I have one more clarification. The FSIS Public Health Veterinarian oversees the whole thing.

Selena Kremer: Let's go to our next question.

Cody Kahlig: Our next question is who stops or slows the line for humane slaughter violations such as live animals on the rail?

Tom Vermeersch: First of all, FSIS would be the one who stops the line and takes regulatory control action for any violation of the Humane Slaughter Act. What is described in the question where I'm going to interpret that question that it is an animal that has gone through this stunning and sticking step and is returning to sensibility on the line. The establishment wouldn't be expected to maintain their stunning procedures and bleeding procedures such that that never happens. In the event that FSIS observes that the line would be stopped and depending upon whether or not it was an egregious violation or not,

FSIS would take appropriate regulatory control action and possibly affect immediate suspension if it was an egregious violation, which this would be.

Selena Kremer: Thanks, Rita. Do we have any more phone calls coming in?

Rita ATT: Yes, we do have a verbal question. Caller your line is unmuted please state your name and go ahead.

Tony Corbo: Yes, this is Tony Corbo for Food and Water Watch. In September 2017, the agency granted a regulatory waiver to a new hog slaughter plant located in Coldwater, Michigan 791C. I'd like to know, what is the difference in the ante-mortem, post-mortem inspection sorting, sampling regime in that plant versus the five HIMP plants?

Tom Vermeersch: The sorting procedures at 791C are modeling what will be done under NSIS.

Tony Corbo: Both ante-mortem and post-mortem?

Tom Vermeersch: Yes.

Tony Corbo: What about the HACCP plants? What are the microbiological and resident testing requirements? Are there differences?

Tom Vermeersch: I'm not sure I understand you.

Tony Corbo: Are there differences in what 791C is doing versus the five HIMP plants in terms of microbiological testing?

Rachel Edelstein: Tony, this is Rachel. They're all under SIP so they all have to do testing for *Salmonella* and indicator organisms, and submit their results to FSIS.

Tony Corbo: All of the plants, they can pick their own indicator organism?

Rachel Edelstein: Yes, if they can support it. Generally, we want them to, okay, *Salmonella*, right.

Tony Corbo: Explain the differences in the ante-mortem and the post-mortem inspection procedures in 791C versus the five HIMP plants? What are the differences?

Tom Vermeersch: The differences are that there is modeling NSIS in the sense that the establishment is conducting sorting procedures. They have prerequisite programs in place. They have a critical control point for ante-mortem conditions and they conduct sorting activities very similar to what Melissa has been describing is what's described in the proposed rule for NSIS.

Tony Corbo: So there are differences in ante-mortem in 791C versus the five HIMP plants?

Rachel Edelstein: We want to get back to the proposed rule.

Tony Corbo: You just said the 791C is modeling NSIS and yet you're using the five HIMP plants to base your NSIS rule and I'm hearing differences.

Rachel Edelstein: We used the HIMP data to propose the rule, so it's all pretty consistent. I mean, I think everybody, every plant that has a waiver has to set up their own protocol and we have to review it, but they're all pretty consistent.

Tony Corbo: They're the same?

Rachel Edelstein: I don't know that they're exactly the same.

Melissa Hammar: Our inspection procedures are the same. What may differ is the establishment has a different line configuration or they choose different microbial sampling. What's different is what the plant chooses, but what we do is the same.

Selena Kremer: Right, thank you so much.

Tony Corbo: I'm still not clear. That's why we need a public meeting because this is very confusing to me.

Selena Kremer: Thank you. Rita, we're going to move our next written question.

Cody Kahlig: Our next written question is routine sampling between August 2010 and December of 2011 should have consisted of approximately 77 samples per plant. Sampling from the 16 non-HIMP plants should've been approximately 1,232 samples. However, table two in page 22 of the risk assessment indicates that there were 3,412 samples collected from the 16 plants during this time. Why the discrepancy?

Lindsay Ward-Gokhale: Hello, this is Lindsay Ward-Gokhale with Risk Assessment again. In order to address the situation that has been described here we needed, we used all data that were available and those are the number of samples that we have in the non-HIMP context. Thank you.

Selena Kremer: Okay, the next question?

Cody Kahlig: Our next question is, why only report on routine sampling from four of the five HIMP plants? What were the results in the fifth HIMP plant?

Lindsay Ward-Gokhale: We reported all the data that we have and for anyone if you didn't have routine sampling, we did have HIMP baseline data for those establishments and would've been using that as well.

Selena Kremer: Rita, do we have any more verbal questions in the queue?

Rita ATT: There are no further verbal questions at this time.

Selena Kremer: Okay, our next written question?

Cody Kahlig: Is the risk assessment that has been referred to be posted in the document on regulations.gov? I can't find it in the docket.

Rachel Edelstein: It should be posted under the proposed rule as a related document. If you go to where the proposed rule is, it should be posted under there.

Cody Kahlig: Okay, next question, in the presentation, it says that FSIS is spending too much time doing non-food safety tasks. What percentage of the time is spent on these non-food safety tasks?

Tom Vermeersch: That's a very hard question to give a definitive answer to because the quality of the animals that come in to any given market hog establishment can vary. Some of them receive pigs that don't have very many of food safety conditions; and therefore, the percentage of non-food safety conditions that they would be directing your trimming up would be quite high relative to the most of the very, very few animals that have food safety conditions. If you have an establishment that's receiving a larger number of animals that have food safety conditions, that percentage would get smaller and smaller. A lot of it is just going to depend on the quality of the animals coming into the facility. Establishments that have HACCP based inspection programs (HIMP) are required to have healthy young animals come into the facility. Part of that is having prerequisite programs in place to assure that only healthy animals arrived. Having the farms PQA certified. Having the truckers that are bringing the pigs to a facility, TQA certified. Having health records on the animals, veterinary certifications. Certifications by third party auditing firms, etcetera. All contribute to the health of the animals coming into these facilities. To answer your question, we do not have a specific number to say how much time they spend on now.

Melissa Hammar: This is Melissa Hammar. I just wanted to add. Yes, in the HIMP report, we concentrated on how much time we were able to save. How much time we're able to use to conduct more offline inspection task.

Selena Kremer: Okay. Let's read the next question.

Cody Kahlig: All right, our next question. How will FSIS ensure plants are adequately training staff to do the ante-mortem and post-mortem sorting?

Melissa Hammar: Similar to what we did for the New Poultry Inspection System (NPIS), we did not propose any training requirements. However, we did post a draft sorting guide on our website. We're requesting comments on that combined for that guide.

Selena Kremer: We have another training question?

Cody Kahlig: What are the requirements for training procedures? The employee sorters?

Rachel Edelstein: That's the answer we just provided.

Melissa Hammar: We provided guidance to help establishments develop their own training program so we did not mandate any training program.

Cody Kahlig: Okay, our next question, is it the inspector or the PHV that has the authority to stop the line?

Melissa Hammar: Both have the authority to stop the line. The PHV is the only one who has the authority to slow the line aside from the establishment. The establishment can choose to stop or slow their line as well.

Selena Kremer: Hi, Rita. We have a question on how to submit a verbal question. Could you go through the instructions again for folks?

Rita ATT: If you like to ask a verbal question, please press pound 2 on your telephone key pad. I do have a verbal question in the queue. Caller your line is unmuted.

Felicia Nestor: Hi, this is Felicia Nestor. I have a couple of follow-up questions too on the routine sampling results. You said that you reported on all of the data that you had. You only had data from four of the five HIMP plants between August 2010 and December 2011. How is it that the agency didn't have any data from a HIMP plant for a year and a quarter?

Michelle Catlin: Hi, Felicia. This is Michelle Catlin speaking. I don't have the numbers in front of me for every plant and the numbers that we have from each plant. I will write that down and we can look into it.

Felicia: Okay, because the issue is the agency cherry picking the data? That actually goes to the routine sampling in the non-HIMP plants as well. Under FSIS routine sampling program, you do 55 samples per year. In a year and a quarter that would be perhaps 77 samples. If you did routine data at 16 plants, that should have been, I don't know what

that is, but that's the 12,032. How you could have had, 2.5 times the number of samples from those 16 plants doesn't make sense. If they were being tested twice as much as other plants and they're not representative and some of this data came trickle down some other plants. That also, skews the data and we don't know that it's reliable. Finally, how did you determine that these 16 non-HIMP plants were representative of the 150 non-HIMP plants? How can we be assured? What steps did you take to ensure that those 16 non-HIMP plants were representative that the data's represented it?

Michelle Catlin: Hi, Felicia. As I said, I don't have all the individual establishment data in front of you, in front of me, but I can assure you as a scientist that I am not cherry-picking data. It's not something I would do.

Felicia Nestor: Okay. I mean, I think that we need more of an answer than that because it really is very, very unusual and doesn't fall along with agency policies if you've got 3,412 samples from 16 plants in one year and a few months. That just violates all of the agencies sampling. We would need to know how that happened. Were the other non-HIMP plants sample that 2.5 times the number the same way?

Michelle Catlin: Felicia, I have the numbers that you sent on your written comment and we will look into this and get back to you.

Felicia: Okay, great. I also have one more question on sampling if you want to take it now.

Selena Kremer: Please go ahead.

Felicia: Okay, table two on page 22, if I understand this table correctly, what is presented is the data from the 35 large and small non-HIMP establishments that the agency for tasks will adopt this new program. The *Salmonella* positive rate for those 35 plants is about four times the rate of the other plant.

Michelle Catlin: Felicia, are you referring to the final row in that table?

Felicia: Yes.

Michelle Catlin: That is a typo that we have already noticed and will be corrected. It is actually about 1.8%.

Felicia: 1.8 okay, and the 93 samples, is that's actually a typo?

Michelle Catlin: That's actually a typo. It should be 933. We found those out afterwards it got posted.

Felicia: That makes a big difference. Okay, thank you.

Rita ATT: We do have another verbal question in the queue. Caller your line's unmuted, please state your name and go ahead.

Patricia Buck: This is Patricia Buck from the Center for Foodborne Illness. This question sort of refers back to the non-food safety tasks that I asked earlier. You said that those non-food safety tasks rely very heavily on the quality of the animals coming into the facility. You made some suggestions to that prerequisites and some other things that are being done to ensure that the animals are healthy, which I appreciate. But, the question to you is, given that the biggest way to really find out your herds are healthy coming into the facility, would be doing some testing of these animals either on farm or in transport or lairage? Is that something that FSIS is hoping that we will comment on?

Rachel Edelstein: Any comments that you want to submit, we would welcome.

Patricia Buck: Because there doesn't seem to be any other opening except for some kind of testing before you actually engage in the slaughtering process.

Tom Vermeersch: It seemed that producers' best interest to have healthy animals and these producers have.

Patricia Buck: We understand that, yes.

Tom Vermeersch: Obviously, they're going to do their best and to have healthy animals. The other thing is that much talk more about non-food safety inspection from the standpoint of online inspection. That's what that slide was referring to. It's not necessarily tasks. It's more has to do with the online inspectors having to spend extra time directing, trimming, looking for non-food spacey type conditions and then directing removal of those. Those are best suited to the plants orders where they can identify those that can be removed under the inspector's direct supervision and then present healthy normal carcasses and parts to the inspector that they can visually observe already to be passed for food.

Patricia Buck: Yes, but that can only happen if they have the training for it. We understand. That's very important. Okay, thank you. I do have one short comment. I do spend a lot of time looking at the research of different things involved with pork slaughter and in the animals as they come into your plants. I really think that a public meeting would've been a better chance for all of us stakeholders to have the opportunity to talk with each other so that we could figure out

which were the most important things to highlight. That's just my comment, thank you.

Selena Kremer: Thank you for your questions and comments. We do have a couple more written questions and of course we do want to get to the remainder of the presentation as well. Let's do a couple more questions and then we can move on with the presentation and we'll have another opportunity to pause for questions again.

Cody Kahlig: Is the less frequent observations of fecal contamination, septicemia, toxemia in HIMP plants because of the plant has sorted these out or because the plant is not identifying as many as FSIS inspectors would have and therefore are missing some?

Melissa Hammar: We look at this in the HIMP report, we compared FSIS condemnation data with the sorter data. We found that they were sorting and removing at about the same, the HIMP report shows at a little bit of a higher level. They're removing carcasses and parts at a higher rate than FSIS combination data shows. They are sorting out these conditions.

Selena Kremer: Okay, we have one more question.

Cody Kahlig: Okay, where are FSIS online inspectors related in HIMP to relation to viscera plant sorters? Are there any other FSIS employees overseeing their work?

Tom Vermeersch: In the HIMP establishment, we have 1 online head inspector. That individual is immediately after the establishment sorters, we got one online veteran inspector. That person is stationed immediately after the establishment sorters. Then we have one USDA final rail inspector that is inspecting the carcasses right before they are going into the final wash.

Selena Kremer: Thank you. We will continue to answer your questions. If you have questions, please continue to let us know. In the meantime, let's go ahead and move to the next slide. It's my pleasure to introduce Lindsay Ward-Gokhale. She's a Toxicologist and Risk Assessor in the Office of Public Health Science Risk Assessment and Analytics Staff. Lindsay?

Lindsay Ward-Gokhale: Thank you, Selena. We're on slide 23 now. Thank you. Separate from the HIMP report and in order to better understand the public health implications of reallocating inspection tasks for more offline procedures, FSIS carried out a quantitative microbial risk assessment in which multiple scenarios were considered. Three categories specific scenarios were created, each of which included adjustment to a single inspection procedure category. The fourth scenario was

created to estimate the impact of adjusting all procedure categories simultaneously as seen in market hog HIMP. Next slide please.

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 records at all market hog plants. The first stage of the model, a regression analysis determines the strength and significance of the relationship between FSIS procedures and the percentage of *Salmonella* positive market hog carcass samples, which we used as an approximation of contamination prevalent. In the second stage, the aforementioned scenarios were constructed in a simulation model which produce estimates of market hogs' attributable *Salmonella* illnesses under the hypothetical offline inspection procedure scenarios. The contamination prevalence to human illnesses relationship had 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 cases from the CDC. The three categories specific scenarios resulted in illness reduction of 1,257 cases, 506 cases and 770 cases. The combined scenario resulted in reduction estimate of 2,533 cases.

Next slide please, overall, the risk assessment improved the agencies understanding of the public health impact of different inspection activities and hog slaughter facilities particularly that a new swine inspection system with increased offline inspection procedure rates would lead to reductions in *Salmonella* contamination and illnesses, most likely around 3.6%. This risk assessment will be peer reviewed and the contract has been awarded. The peer review will begin shortly and it will take a few months to receive and respond to the comments from those reviewers. Thank you. I'll give the floor back to Selena.

Selena Kremer: Thank you, Lindsay. I see that we already do have one written question in the queue.

Cody Kahlig: The question is, when will the peer review of the risk assessment will be available?

Lindsay Ward-Gokhale: We do not have an exact date on when the review will be available, however it will be beginning shortly because the contract has already been awarded. We expect that it will take a few months.

Michelle Catlin: Further explanation, we have to provide time to the contractor to be able to identify the peer reviewers. They have to have time to review the documents and then get the comments back to us and then we have to respond to the peer review comments once we've received them. That gives you some idea of why it takes that long.

Selena Kremer: Rita, we can go ahead and open the lines for any questions on this portion of the presentation.

Rita ATT: Just to remind our audience pressing pound 2 will enter us into the verbal queue. We do have a verbal question. Caller your line is unmuted, please state your name and go ahead.

Tony Corbo: Tony Corbo, the peer review is going to be available after the comment period closes. Now, how does that jive with the OMB requirements that when you propose a rule and has a risk assessment that the peer review should be part of the package that you present for comments?

Lindsay Ward-Gokhale: Yes, in this case, the risk assessment actually follows the same procedures, the same approach that we use for the poultry slaughter risk assessment. That poultry slaughter risk assessment has been peer reviewed as well as the majority of the methods that were used in it have actually been published in the peer reviewed literature. It's a very similar approach, almost the exact same approach for this as well as for poultry slaughter. In the interest of time, we went ahead and put this out publicly before the peer review.

Rachel Edelstein: OMB did clear it.

Lindsay Ward-Gokhale: Yes, OMB did say that was fine.

Rachel Edelstein: I think we've also clarified if we do need to make significant changes to it, we would open up the comment period on it again.

Tony Corbo: Thank you.

Lindsay Ward-Gokhale: Another comment saying, will the peer review document be submitted to the record for public comment? As with previous risk assessments, I believe the peer review comments and our response to them are posted on our website that I will confirm that.

Cody Kahlig: The next question is why didn't FSIS follow OMB suggestions to do the peer review before writing the proposal?

Lindsay Ward-Gokhale: I think we just addressed that and said that OMB cleared it as it was and knew when we were doing the peer review.

Selena Kremer: Any other verbal comments, Rita?

Rita ATT: There are no further verbal questions.

Selena Kremer: Thank you so much.

Selena Kremer: Now we'll turn the presentation back over to Melissa Hammar.

Melissa Hammar: Thank you, Selena. Now we're on slide 27 and we'll be going over the key elements of the proposed NSIS. FSIS proposed to require establishment personnel to sort and remove unfit animals before ante-mortem inspection by FSIS and determine, identify defects on carcasses and parts before FSIS post-mortem inspection. This is consistent with the HIMP program. We also to propose to require establishment personnel to identify animals that they have sorted and removed for disposal before FSIS ante-mortem inspection with the unique tag tattoo or similar device and immediately denature all major portions of the carcass on site. To maintain records to document the total number of animals and carcasses sorted before FSIS ante-mortem inspection and post-mortem inspections per day. This is again, consistent with HIMP and we went over the record keeping site before it. We also proposed to require establishment personnel to immediately notify FSIS inspectors if they suspect ante-mortem carcass with reportable or foreign animal disease while conducting sorting activities. I would just like to note that these foreign animal disease issues are extremely rare. We only propose this out of an abundance of caution. Just to make sure that FSIS inspectors are able to find out about issues as quickly as possible.

Let’s turn to the next slide to key element four. We proposed to shift agency resources to conduct more offline inspection activities that are more effective in ensuring food safety, which would allow for up to 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 proposed to require establishments to maintain records documenting that products resulting from their start of operations with the new proposed definition of ready to cook pork product, which we proposed to define as any slaughtered pork product free from bile, hair, scurf, dirt, hooves, toe nails, claws, bruises, edema, scabs, skin lesions, extraneous foreign material and odor and which is suitable for cooking without need of further processing. Finally, we proposed to revoke maximum line speeds in authorizing establishments to determine their own line speeds based on their ability to maintain process control for preventing fecal contamination in meeting microbial performance measures during slaughter operations.

Let's turn to the next slide, which is a diagram of ante-mortem floating under the proposed NSIS. Pretty much the same exact sorting procedures are done under the HIMP program. Establishments are required to sort healthy hogs into normal pens and animals that may be exhibiting disease conditions into U.S. Suspect pens where they are subject to additional FSIS inspection. We look at normal pigs, 100% at rest in 5 to 10% motion and we looked at a 100% of the suspect pigs are resting in motion. The FSIS PHV assesses whether the pigs in the U.S. Suspect pen can move onto the setting process. Just like HIMP, we have a zero tolerance for food safety conditions before the stunning process. If the FSIS PHV determines that the establishment did not properly sort according to their procedures, they would receive a noncompliance record.

Let's move to the next slide. I think the slide addresses some of the questions we had about what online inspection will look like. This is again based on the configurations in a large high-volume establishment. From what we've heard from establishments, they typically have three plants sorters and one FSIS online inspector at the head inspection station. Three plants sorters at the viscera station and one FSIS online inspector, and three plants sorters at the carcass inspection station with one FSIS online inspector. We again propose to have up to two offline inspectors conducting offline activities and one Public Health Veterinarian that oversees the whole process.

Let’s move to the next slide. This is just a summary of the differences between traditional and the proposed NSIS. Proposed NSIS is based on HACCP principles which require establishments to develop procedures to identify hazards earlier and at various points in slaughter and production process. The role of FSIS and or traditional inspection is not compatible with these HACCP principles since establishments have no responsibility during ante-mortem and post-mortem process for controlling food safety hazards and quality defects associated with animal diseases. FSIS is still very much in control of identifying new defects. We're almost controlling their process control by identifying quality defects. Under NSIS, establishments will be required to take ownership of their food safety aspects associated with ante-mortem and post-mortem. FSIS will inspect the process and document noncompliance when it occurs. Again, only in both traditional and proposed NSIS and HIMP, only FSIS can inspect. Only FSIS can condemn animals, carcasses and parts.

Let's turn to the next slide where the summary continues. Under NSIS, establishments are again required to identify interim defects on carcasses and parts before FSIS inspection. NSIS allows establishments to consolidate inspection station. Otherwise they configure the evisceration lines in order to make room for more innovative automated equipment and it allows establishments to operate in faster line speeds and also to be able to maintain process control by preventing fecal contamination and if they're meeting microbial performance measures.

Let's move to the next slide. The next slide, these are the proposed changes for all swine slaughter establishments. FSIS is proposing to require that all official swine slaughter establishments develop, implement and maintain in their HACCP systems written procedures to prevent contamination of carcasses and parts by enteric pathogens, fecal material, ingesta and milk throughout the entire slaughter ingesting operation. These procedures must include sampling and analysis for microbial organisms to monitor process control for enteric pathogens, as well as written procedures to prevent visible fecal material, ingesta and milk contamination. We proposed to remove the current requirements to test carcasses for generic *E. coli* to monitor process control and to replace them with new testing requirements, which allow establishments to create testing requirements that are more tailored to their own processing environment. We've also proposed to remove the codified *Salmonella* and Pathogen Reduction Performance Standards for Swine because we've determined that verification sampling is a not a good use to FSIS resources.

Can we move to the next slide? We proposed a minimum frequency in which establishments would be required to collect two samples. One at pre-evisceration and one at post-show or for very small and low volume establishments, a single post-show sample. Establishments except for very small and very low volume establishments will be required to collect pre-evisceration and post-show samples at a frequency of once per 1000 carcasses. Its frequency mirrors the existing regulations for generic *E. coli* and testing. For very small and very low volume establishments, we've proposed that they would be required to collect at least one sample during each week of operation each year if after collecting 13 weekly sample, very small and very low volume establishments can demonstrate that they are effectively maintaining process control. They can modify their sampling to collect samples less frequently. Finally, we've proposed to allow establishments to substitute alternative sampling locations and alternative sampling frequencies. We've published a draft compliance guide on all of these new

proposed sampling requirements and we're requesting comments on that sampling on the compliance side.

We move to the next slide. We've also proposed that establishments 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, reuse water and equipment, including knives, and edible food production departments before slaughter operations began. This proposed requirement, that we may extend to other species in subsequent rulemaking depending on comments on whether we're able to finalize and implement this requirement. We are requesting comments on this proposed change. These procedures must include sampling and analysis of food contact surfaces in the pre-operational environment from microbial organisms to ensure that the surfaces are sanitary and free of enteric pathogens. The sampling frequency must be adequate to monitor the establishment's ability to maintain sanitary conditions in the pre-operational environment.

On the next slide, I mentioned before that we posted a compliance guidance on our sorter guide for establishments to help them train their sorters. We've also developed compliance guide for these new sampling requirements. We are requesting comments on both of these guides.

Selena Kremer: Okay, I think we're going to pause here for a few questions. I see we have a few coming in on the written queue. Let's go ahead and start with one of those first.

Cody Kahlig: The question is, what happens to the animals who are marked as U.S. Suspect and don't go to slaughter?

Tom Vermeersch: The regulations for that are found in 9 CFR 309, an establishment can, under FSIS' direct supervision, keep the animal at the facility for treatment and then represent the animal after they've determined that the animal has been adequately treated because there would be nothing that would change in the regulations as far as NSIS would be concerned with that.

Selena Kremer: Thank you. Rita, do we have any verbal questions?

Rita ATT: We don't have any verbal questions at this time, but just a reminder to our audience, press pound two if you'd like to ask a verbal question.

Cody Kahlig: The *Salmonella* species are quite different and virulent to humans as well as to swine, poultry, et cetera. Reducing all *Salmonella* is nice but reducing *Salmonella* strains linked to outbreaks would seem to have a greater effect on public health. Has FSIS considered that since the first recommendation by the NACMPI in September of 2011, "One agency in collaboration with stakeholders should identify these *Salmonella* strains of highest public health concern and prioritize their control in pre- and post-harvest consideration?"

Rachel Edelstein: All right, first I just want to point out that the only thing we specifically propose related to *Salmonella* in the rule was to remove the codified performance standards. We have an exploratory program ongoing right now where we're testing for *Salmonella* and other organisms for pork products. We're certainly analyzing that data. In the policy office, we've put out some guidance on how to address *Salmonella*. Then I'm going to turn this over to OPHS for some additional updates.

Lindsay Ward-Gokhale: Yes, specifically focusing on the relationship between *Salmonella* contamination writ large on market hog carcasses in human illnesses with salmonellosis, that is a relationship that we have previously published on in the scientific literature while it is true that there are a variety of different characteristics of *Salmonella* that are related to virulence and we're continuing to always investigate ways that we can better understand and apply that knowledge to our regulatory paradigm. This particular relationship between *Salmonella* contamination and human illnesses is well established and exist in the peer reviewed literature. Thank you.

Selena Kremer: Thank you. Let's go to our next written question.

Cody Kahlig: The question is, what is the rationale for requiring one sample per 1000 carcasses? How many environmental samples will be required?

Melanie Abley: Hi. This is Melanie Abley from OPPD. For the one for the one to 1000, that was based on our previous generic *E. coli* requirements. Then for the environmental, for the pre-op, all of that information can be found in the compliance guide that was included as part of the rule for comments. There's a table that includes the frequencies on page 17. You're welcome to go and look at that and provide comments.

Selena Kremer: Thank you. Rita, do we have any verbal questions in the queue?

Rita ATT: We don't have any verbal questions at this time.

Selena Kremer: Okay, we'll go ahead and go to the next written question then.

Cody Kahlig: In regards to 9 CFR 310.25, when our very small, low volume establishment harvests a greater number of beef than swine and the choices made to remain within traditional inspection, will the NSIS sampling requirements mean the establishment needs samples both swine and beef during the 13-week sampling period?

Melanie Abley: This is Melanie Abley again. As per our current regulations, whichever species they harvest in the highest number that year is what they would need to sample for.

Melissa Hammar: This is Melissa Hammar, I'd like to clarify that the proposed sampling requirements that we went over are not just for establishment that volunteer to operate under NSIS. The sampling requirements are for all swine establishments.

Selena Kremer: Thank you. Our next written question?

Cody Kahlig: The question is some of the statements on the slides indicate that there will always be 2 offline inspectors per slaughter line. The verbal explanation indicated that there would be up to two offline inspectors. If it is up to two offline, would it trigger a second offline?

Melissa Hammar: In the HIMP model, we used two offline inspectors. We say up to two in a role because just in case an establishment decided to add another line. There may not be enough work for four offline instructors. It all depends on workload and how the establishment is set up.

Cody Kahlig: The next question is since OIG audit in 2013, have there been any other external audit to evaluate HIMP?

Rachel Edelstein: No, I don't think so. I'm pretty sure not.

Selena Kremer: Thank you. We don't have any more written questions? Rita, do we have any verbal questions?

Rita ATT: Not as this time.

Selena Kremer: Okay, great, let's go ahead and move on to slide 37. I'd like to introduce Andrew Pugliese. He's an economist in the Office of Policy and Program Development Policy Analysis Staff. Andrew?

Andrew Pugliese: Hello, good afternoon. I'm here to present on the economic analysis for the proposed rule, for which we use 2016 as the base year. During that year, there are approximately 612 swine slaughter establishment under federal inspection that slaughtered approximately 118 million hogs. Forty of these establishments exclusively slaughtered market swine were considered high volume that are accounted for over 92% production. The remaining 522

establishments slaughtered a variety of swine subclasses were a mix of high and low volume and accounted for less than 8% of production. For the purposes of this analysis, we assume that these 40 establishments would adopt NSIS and the remaining 532 will not adopt NSIS.

Moving on to slide 38 please. The per cost analysis, the voluntary cost are the first broad cost category covered with this analysis. Overall the annualized costs of the NSIS program, which is voluntary, it was calculated that roughly $17.02 million, assuming a 3% discount rate over ten years. These costs are result of increased establishment labor needs associated with online sorting, which has an annualized cost of roughly $16.16 million. In addition to that labor, we also assumed that increased labor demands associated with meeting ready-to-cook standards, which has an annual cost of roughly $299,000. These cost increases are incurred by the two of 22 large and 13 small, high-volume establishment expected to voluntary convert NSIS. It's worth noting that the five large HIMP establishments that have already incurred the increases in cost associated with NSIS were not included in this portion of the cost analysis.

Moving on to slide 39. The mandatory costs were the second broad cost category associated with this review. Overall, the annualized cost of the mandatory requirements were roughly $881,000 assuming a 3% discount rate over ten years. These costs are associated with establishing and implementing sanitary dressing plans, which have an annualized cost of $1.5 million. Modernizing process control sampling programs for microbial organisms, which have an annualized cost savings of $756,000, in sampling the slaughter environment for microbiological contamination, which has an annual cost of $81,000. The mandatory costs of the proposal are expected to be applied to all 612 swine slaughter establishments.

Moving on to slide 40. This analysis also estimates to quantified economic value under proposed rules accepted health benefits and benefits from increasing industrial efficiency. The hog risk assessment estimates that if the 35 establishments expected to convert to NSIS do so, the NSIS would reduce human illnesses attributed to products derived from market hogs for an average of about 2,533 *Salmonella* illnesses annually. Such a decrease of illness for the potential cost reduction of $9.33 million annually. Based on the evaluation of HACCP Inspection Models Project (HIMP) for market hogs report, the HIMP establishments average line speeds were approximately 12.5% faster than comparable establishments. Assuming all 35 establishments expected to adopt NSIS increased in

line speeds initial benefits would increase by roughly $47.33 million annually.

Moving on to slide 41. This analysis estimates the changes to the agency's budgetary requirements associated with the NSIS. Overall, the NSIS is expected to reduce agency budgetary needs by roughly $6.3 million annually. These changes take into consideration, changes to agency staffing, which has an annual cost reduction of $6.67 million dollars. Training agency staff on NSIS method, which is the annualized cost of $68,000 and converting food inspectors into consumer safety inspectors, which has an annualize cost of $229,000. These changes occur at the 22 large and 13 small hog volume establishments expected to voluntary convert to NSIS.

Moving on to slide 42. Here we have a snapshot overview of the net costs and benefits for the proposed rule. What's worth pointing out is that the annual cost savings, which including health benefits was valued at $31.77 million dollars.

Moving on to slide 43. Our analysis also took into consideration the Executive Order 13771, which is reducing regulation and controlling regulatory costs. Consistent with E.O. 13771, we've estimated that this proposed rule would yield the cost savings of approximately $24.97 million not including health benefits. Therefore, if finalized as proposed, the rule is expected to be an Executive Order 13771 deregulatory action.

Selena Kremer: Thank you, Andrew. Rita, can we go ahead and open up the lines for verbal questions?

Rita ATT: We do have a verbal question. Caller, your line's been unmuted. Please state your name and go ahead.

Tony Corbo: Yes, this is Tony Corbo from Food and Water Watch. Andrew, one of the things I saw missing here was the training costs to train the sorters by the companies. A couple of things, first of all, that guidance document that you all have provided is very technical. It's only in English and then as you know, a lot of these slaughter facilities employ folks where English is a second language, if they speak it at all. Did you take into account what it's going to cost to translate the guidance document into other languages? Not only Spanish, but you have folks from Somalia, Ethiopia. Folks from Cambodia who work in these plants, number one. Number two, because there's high turnover in these meat packing plants, how frequently do you think the training is going to have to be done? What will be the cost for that?

Andrew Pugliese: Tony, I would say the cost for training establishment employees was considered in the economic review. We assumed that the training would happen on a yearly basis. We even included the training requirements for lost employees. So annual attrition of employees training them on an annual basis was considered. Those costs are included in my analysis.

Tony Corbo: Including translating the document to other languages?

Andrew Pugliese: Tony, I don't know what is… What we do is we looked at how much establishments spend on training already for similar programs. Depending on what those establishments decide to do for their individual labor forces, to the extent that it includes translations and that's included.

Tony Corbo: You found that they only train once a year?

Andrew Pugliese: Establishments have both on-the-job training, which was I would imagine is continuous, as well as specific annual training programs.

Tony Corbo: You're asking folks to make some veterinary judgments on ante-mortem then you're adding them to… What do you mean you're not? You were asking them to sort.

Tom Vermeersch: We're asking them to identify abnormalities, we're not asking them to diagnose disease.

Tony Corbo: How are they supposed to diagnose abnormalities?

Tom Vermeersch: When you work in a facility.

Tony Corbo: We're going to have a disagreement on that.

Selena Kremer: Thank you so much for your question. We do have a written question here. Let's move to our first written question.

Cody Kahlig: The next question is from Cindy Clug and she says that she understands the sampling is for all establishments and that she hears the greater number of species would remain as-is in 9 CFR 310.25. For an establishment that harvests both species, would they need to sample both with a very small, very low volume sampling expectations?

Melanie Abley: Hi, this is Melanie Abley. There are two ways I can read this. The first way is if they harvest both species, would they need to sample for both? If you mean by both species, say B for swine, no, they would only be required to sample the one that is harvesting the highest number. However, if you are referring to both as in the two

sampling points, that would only be required if they had swine in the highest volume.

Melissa Hammar: Right, so if you're slaughtering beef in the highest number, you would continue doing what you're currently doing. If you're slaughtering swine in higher number, you would follow what's in this proposed rule. Should it go final.

Selena Kremer: Okay, thank you. Let's go to our next written question.

Cody Kahlig: The next question is, the proposed rule says FSIS established a humane handling coordinator in response to the 2013 OIG report but hasn't FSIS had a humane handling coordinator since at least 2010?

Michelle Catlin: I'm not part of the humane handling part of the agency but I can tell you, we have a press release from October 2013 where we talked about we recently established and created the humane handling enforcement coordinator position. It could've been that there was an ombudsman position before that you're thinking about.

Selena Kremer: Thank you, Michelle. Our next written question.

Cody Kahlig: To verify the anticipated decrease in salmonellosis, does FSIS' proposal includes sending positive results to CDC for analysis?

Lindsay Ward-Gokhale: Thank you for your question. This is not part of the rule in terms of modifying any of our foodborne illness surveillance procedures. Human foodborne illness surveillance will continue unchanged as well our collaborations with our food safety partners, federally, including CDC.

Selena Kremer: Let's go to our next written question.

Cody Kahlig: Is the economic analysis of the rule posted in regulations.gov? I cannot locate it.

Andrew Pugliese: The economic analysis is part of the proposed rule. It is the 12866 section of the proposed rule. If you have the proposed rule, you have the economic analysis as well.

Selena Kremer: Thank you. Next written question.

Cody Kahlig: Do any of the HIMP plants keep data on the numbers of animals sorted out for specific reasons? Example septicemia, toxemia, CNS? This data now goes into PHIS but under NSIS, will not be in PHIS. Will NSIS establishments keep these records in house?

Melissa Hammar: Under HIMP for right now, they only give us the total numbers, but we are aware that's some establishments are keeping their own records and we have asked for comments on this to see whether or not they would be willing to share that information or able to share that information so that we can share that information with APHIS.

Cody Kahlig: Our next question is for NSIS, how does FSIS define process control? What actions would FSIS take to ensure process control is maintained?

Melissa Hammar: Under the proposed rule, FSIS would verify the effectiveness of an establishment's process control procedures and preventing carcasses from becoming contaminated with enteric pathogens, fecal material, ingesta, and milk. By reviewing the establishments monitoring records, including the establishment's microbial testing results. Observing establishments implementing their procedures and inspecting carcasses and parts for a visible fecal, ingesta, and milk contamination when conducting both online and offline verification procedures. Establishments have to meet both food safety and non-food safety standards. If inspection personnel determine that an establishment's process control procedures are not effective in preventing contamination by enteric pathogens, fecal material, ingesta, and milk, the agency will take appropriate regulatory actions to ensure that the establishment's production processes are in control. Such actions would include performing additional, visual inspection of products, increasing offline verification inspections, initiating food safety assessments, conducting additional hazard analysis verification procedures and retaining or condemning products. We did provide additional information in the compliance guide on ways establishments can monitor their process control. Melanie, do you want to talk about that a little bit?

Melanie Abley: Sure, they definitely need to be taking into account their whole process when they're looking at that. Specifically, for the micro, there are different graphs and there are different examples that we give for how establishments can develop their statistical process control and different things that they can do to bring those back into compliance.

Selena Kremer: Thank you. We have another written question.

Cody Kahlig: Next question is, given that healthy animals can carry pathogens that cause human illness, does this rule include routine inspection of lymph nodes and other high-risk organs?

Tom Vermeersch: The answer to that question is yes. FSIS will continue to inspect lymph nodes of heads, carcass, viscera, all parts of the carcass and lymph nodes to determine that the animal is wholesome and fit for production into human food.

Selena Kremer: Thank you. I'm not seeing any more questions in the written queue. Let's move ahead to slide number 44, Melissa.

Melissa Hammar: Sure. Again, the rule is published on our website and also at regulations.gov. Comments are due on May 2nd. Please go to regulations.gov or you may submit comments by mail or you can hand-deliver them on to us here at headquarters.

Selena Kremer: Thank you. Let's take this opportunity as we close the presentation for any final questions verbally or written.

Rita ATT: We do have a verbal question. Caller, your line's been unmuted. Please state your name and go ahead.

Selena Kremer: We're listening.

Tony Corbo: This is Tony Corbo again. On the process control issue, I noticed as a result of FOIA I filed on that plant in Michigan that the plant had had issues with a whole several carcasses where the toenails were not removed properly. And an NR was filed against the plant. Is that a process control issue?

Melissa Hammar: It’s not really related to this rule and it's also not related to food safety. That's another consumer protection defect.

Tony Corbo: If an other consumer protection issue comes up repeatedly because the evisceration process is not being done properly, that's not lack of process control then?

Melissa Hammar: No, we verify OCPs by doing 24 carcass checks and we verify their process over time for OCPs and if we see anything that demonstrates that the process is out of control, we will take the appropriate regulatory control actions either slowing or stopping the line or railing out the defective carcass or part.

Tony Corbo: It is a process control issue then? It's just not limited fecal contamination or milk or ingesta. There are other issues that come up. I would like an explanation of what process control is because that is another issue that is very vague.

Melissa Hammar: They have to meet the food safety and non-food safety performance standards. They have to meet the ready-to-cook standard which means that product does not need additional preparation. It is ready-to-cook. If you go back to the HIMP slide, you'll see that chart,

which is how we monitor OCPs. It also shows when we issue NRs. Just one toenail does not necessarily mean we're going to condemn the whole carcass because there are steps along the line for the establishment to continue sorting and to remove defects.

Tony Corbo: I'm saying in the case of the Michigan plant, there were several carcasses in a row that the inspectors found that the toenails were not being moved properly. It's not just one toenail.

Tom Vermeersch: In those circumstances, the inspectors are to notify the PHV. The PHV determines that their presentation fails or not then takes appropriate regulatory control based on his good judgment and following the instructions in FSIS Directive 6100.2.

Tony Corbo: Right, okay, thank you.

Selena Kremer: Thank you for your questions. We do have one more written question.

Cody Kahlig: When did OMB approved the peer review process for this rule?

Lindsay Ward-Gokhale: We have worked with OMB throughout the process of preparing the draft risk assessment and they did approve this particular process could be used before the docket was published, thank you.

Selena Kremer: Okay, and a verbal question?

Rita ATT: Caller, your line's been unmuted. Please state your name and go ahead.

Celeste Montefort: Hi, this is Celeste Montefort at Texas State University. I have a question regarding the worker's safety provisions over the rule. The proposal and the preamble just described some comparisons and injury rates between HIMP and traditional swine plants and I can't find that analysis in the docket anywhere. Has that been made available so it can be reviewed and commented on?

Rachel Edelstein: The information, the data is discussed in the proposed rule. We didn't post the raw data.

Celeste Montefort: Okay, the extent of the analysis is what is in the proposed rule in the preamble?

Rachel Edelstein: Right.

Celeste Montefort: Thank you.

Melissa Hammar: Yes, but we did request comments on that. If you have additional information, feel free to submit it.

Celeste Montefort: Yes, I guess the comment was, it's hard to comment on an analysis when you don't have the analysis of worth of data to examine. Would you consider putting the analysis in docket so it can be commented on?

Rachel Edelstein: I think this is the analysis is what I'm saying.

Celeste Montefort: We can't determine what the plants were that were used as the comparison in case we wanted to do our own analysis because you really just don't comment on something you don’t know.

Rachel Edelstein: Yes, we typically don't provide the specific names of establishment in the case like this.

Selena Kremer: Okay, thank you. It looks like we do not have any more written questions. Rita, before we go ahead and end today's webinar, do we have any final verbal questions?

Rita ATT: No, we do not.

Selena Kremer: Okay, great. Thank you. I want to thank the audience for being so engaged today and thank our speakers for being here and for providing the overview of the proposed rule. Thank you, have a great afternoon.

Rita ATT: Thanks for joining today’s conference. The call has now concluded and you may disconnect.

[END OF TRANSCRIPT]