

FSIS Webinar on Eliminating the Regulatory Requirements for Trichinella Spiralis in Pork Products.
~ July 17, 2018

[START OF TRANSCRIPT]

Aasif, ATT Moderator: Welcome, everyone and thank you for joining today's FSIS Webinar on "Eliminating the Regulatory Requirements for Trichinella Spiralis in Pork Products." You are welcome to submit written questions throughout this presentation and these will be addressed during Q&A. To submit a written question, please use the chat panel on the lower right-hand side of your screen and then choose All Panelists from the send-to dropdown menu. If at any time you require technical assistance, please send a note to the event producer or call our helpdesk at (888) 796-6118. With that, I'd like to turn the call over to Autumn Canaday with FSIS.

Autumn Canaday: Good morning. Thanks for dialing in to today's webinar on "Eliminating the Regulatory Requirements for Destroying Trichinae in Pork Products." We want to use this opportunity to offer background and discuss the FSIS compliance guideline for the prevention and control of trichinae and other parasitic hazards in pork products.

Before we start the webinar, I want to let you know that this webinar is being recorded and FSIS will make the recording and transcript available on the Meetings and Events page on the FSIS website. Now, let's get started with the webinar. I'd like to first introduce Melissa Hammar, who serves as the Deputy Director of the Issuances Staff for the Office of Policy and Program Development. I also want to introduce Dr. Meryl Silverman, who serves as Senior Staff Officer with the Office of Policy and Program Development. Melissa.

Melissa Hammar: Thank you, Autumn. If you move to slide three, you'll see an outline of this presentation. I'm going to start with the background on the rulemaking, then go over the compliance guide and some frequently-asked questions.

Let's get started and move to slide four. I'll start with the 2001 proposed rule. On February 27, 2001, FSIS published a proposed rule in the Federal Register. We proposed food safety performance standards for all ready-to-eat and all partially heat-treated meat and poultry products. We also proposed to rescind the requirements in the meat inspection regulations that prescribe treatments of pork and pork products to eliminate trichinae because the requirements are inconsistent with the Hazard Analysis and Critical Control Point (HACCP) regulations.

We further proposed to require that all thermally processed, commercially sterile meat and poultry products be processed to either eliminate or control the growth of *Clostridium botulinum*, depending on the pH of the product or other factors affecting the growth of that pathogen. Finally, the agency proposed that each establishment that produces ready-to-eat meat and poultry products would have to test food contact surfaces for *Listeria* species to verify the efficacy of its sanitation standard operating procedures

FSIS Webinar on Eliminating the Regulatory Requirements for *Trichinella Spiralis* in Pork Products.
~ July 17, 2018

unless it had incorporated one or more controls for *Listeria monocytogenes* (*Lm*) into its HACCP plan. FSIS later addressed *Lm* separately in the interim final rule published in June 2003, and affirmed the interim final rule with minor changes on June 2015.

We can move to the next slide. Let's talk about the supplemental proposed rule. Because of the length of time since the publication of the 2001 proposed rule, FSIS published a supplemental proposed rule on March 28, 2016, to provide the public an additional opportunity to comment. In the supplemental proposed rule, FSIS only addressed the proposed changes to the regulations on the control of trichinae in pork products and on thermally processed, commercially sterile meat and poultry products. FSIS withdrew the other provisions of the 2001 proposed rule because the agency's current regulations and inspection program have been effective at preventing adulterated RTE product from entering commerce.

In the supplemental proposed rule, FSIS re-proposed the changes to remove the trichinae requirements, which is consistent with what we proposed in 2001. FSIS explained that if the supplemental proposed rule was finalized, FSIS would end its *Trichinella* Approved Laboratory Program for the evaluation, and approval of non-federal laboratories that use the pooled sample digestion technique to analyze samples for the presence of trichinae. In addition, rather than what FSIS proposed in 2001, the agency proposed to combine the meat and poultry canning regulations into a new part of the regulations and to make minor changes to improve the clarity and remove redundant sections.

Next slide. FSIS received 11 comments in response to the supplemental proposed rule. All but one of these comments supported the proposal to eliminate the prescriptive trichinae control regulations. One individual opposed the proposal because, according to the commenter, the trichinae control regulations are effective. Only comments from a trade association representing meat processors, and a trade association representing shelf-stable food processors, addressed the proposed changes to the thermally processed, commercially sterile regulations. Both comments supported the proposal to consolidate regulations. After reviewing the comments, FSIS finalized the supplemental proposed rule with one small change. Specifically, we updated the cross reference in the Siluriformes fish regulations to reference the new canning regulations. The final rule will be effective on July 30, 2018.

We can move to the next slide, final summary of the final rule. With the final rule, FSIS removed 9 CFR 318.10. Now, under the final rule, establishments producing pork products will have to determine whether *Trichinae* is a hazard reasonably likely to occur in their processes. If it is, they must address the hazard in their HACCP plan including critical control points

FSIS Webinar on Eliminating the Regulatory Requirements for Trichinella Spiralis in Pork Products.
~ July 17, 2018

designed to control parasitic hazard and critical limits that must be met at HACCP.

Establishments are also required to maintain supporting documentation to justify the decisions made in their hazard analysis. Paper-supporting documentation depends on the hazard, the establishment, and the justification for the decision. For example, a pre-requisite program may be used for the decision that a hazard is not reasonably likely to occur because the program prevents conditions that makes the hazard likely. Where appropriate, other supporting documentation may be used to justify that a hazard is not reasonably likely to occur such as scientific evidence, establishment historical record or other establishment generated data.

FSIS inspectors will verify that establishments are following their HACCP plans and pre-requisite programs and that their HACCP plans and pre-requisite programs are effective at preventing or controlling for trichinae. FSIS ended its Trichinella Approved Laboratory Program (TALP) to make more efficient use of its resources. As FSIS explained in the proposed rule and final rule, there is only one laboratory enrolled in the TALP program. Under the final rule, establishments may test product samples for the presence of trichinae using any validated testing method that is equivalent to the pooled sample digestion technique to verify that their system is working. Establishments may enroll in the Agricultural Marketing Service's Trichinae Export Program, which tests for trichinae using the artificial digestion technique. Consistent with other industry testing, FSIS will not provide oversight of third-party testing and will not provide protocols for industry testing.

Finally, FSIS consolidated the regulations on thermally processed, commercially sterile meat and poultry products. They're now located in the new part 9 CFR part 431. Next slide. To assist establishments in understanding the available options that are effective for the prevention and control of trichinae in ready-to-eat and not-ready-to-eat pork products, FSIS developed a compliance guide. The guideline was finalized and issued along with the final rule. The guideline takes into account comments on the supplemental proposed rule in draft compliance guide issued in 2016. Now, I'm going to turn this over to Dr. Meryl Silverman. She'll go over the compliance guide and the frequently asked questions.

Meryl Silverman:

Thank you. Again, this is Meryl Silverman. Before going over the different options in the compliance guideline on the next slide, we want to clarify the different types of pork products produced and how trichinella is addressed in the hazard analysis based on the type of product. Under HACCP, most establishments may determine that trichinella is not reasonably likely to occur in fresh raw pork products produced from confinement-raised market swine because those products are customarily well-cooked, and the

products bear safe-handling instructions. Such products that aren't customarily well-cooked include fresh pork, those that are the raw or uncured, as well as fresh unsmoked sausage containing pork muscle tissue and bacon and jowls that were previously listed in 9 CFR 318.10(a).

If an establishment is producing raw pork, determine that trichinae is not reasonably likely to occur. Because consumers customarily cook these products, they do not need to follow any of the options in the compliance guide because they've supported their decision using scientific evidence. In addition, when FSIS removed 9 CFR 318.10(a)(1), it did not create a new requirement for establishments to use validated cooking instructions on their labels of fresh raw pork products. However, if establishments voluntarily choose to use cooking instructions on their labels, they must be validated.

On the next slide, there are certain other less commonly produced pork products, however, that are not customarily well-cooked or that present an added risk of infection with trichinella. For these other products, establishments need to prevent or control trichinella through either a pre-requisite program or a critical control point and would use one of the options in the compliance guideline as support for its decision making. These other products include pork products that are prepared in such a manner that the product might be eaten rare or without further cooking because the appearance of a finished product makes it hard for the consumer to visually determine if the product has been fully cooked. Examples of these products include ham, smoked sausage and pork shoulders. These are the products that have been under 9 CFR 318.10(b).

On the next slide, the trichinella compliance guideline has available options that are effective for the prevention and control of trichinella in the types of ready-to-eat and not-ready-to-eat pork products. That is with other types of not-ready-to-eat products that are not customarily well-cooked. These options are shown in the table on the slide and include option one to acquire pork products from carcasses or carcass parts found to be free of trichinella by a validated testing method. Option two, to obtain pork products from swine producers who participate in the Trichinae Certification Program or a negligible risk compartment for trichinella. Option three, to label not-ready-to-eat pork products, including all forms of fresh pork requiring additional treatment by the consumer -- again, those are products that have been in 318.10(b) with validated cooking instructions. Option four, to treat not-ready-to-eat pork products for the destruction of trichinella that might be eaten rare or without thorough cooking because of the appearance of the finished product using heating, freezing, curing, high pressure processing or irradiation. Then, last, option five, to develop alternative trichinella control procedures not included in option four. That is to validate

an alternative procedure from one that FSIS includes in the compliance guideline.

With that overview, we did want to go over some commonly asked questions. The first one we've commonly received is after the implementation of the final rule. Do all establishments that process swine need to consider trichinella a hazard as either reasonably likely to occur or not reasonably likely to occur? The answer to this is yes. This is consistent with previous FSIS policy associated with trichinella. However, FSIS anticipates there should be little to no change for establishments as they were previously required to address trichinella in the hazard analysis prior to the implementation of the final rule. Importantly, establishments that produce fresh raw pork products from confinement-raised swine such as the fresh pork raw or uncured, as well as fresh unsmoked sausage containing pork muscle tissue, and bacon and jowls that were previously listed in 318.10(a) may support trichinella, but is not reasonably likely to occur with the justification that these products are customarily well-cooked and the products bare safe food handling instructions.

On the next slide, another question we've commonly received is that after the implementation of the final rule, can an establishment making a product prepared in such a manner that it might be eaten rare, or without thorough cooking because the appearance of the finished product, make it hard for the consumer to visually determine it's been fully cooked? Again, those products that have been in 318.10(b) such as ham, smoked sausage, and pork shoulders, can they rely on special labeling to support its decision that trichinella is reasonably likely to occur? The answer to this question is yes. Establishments producing these types of products that give the appearance that could result in them being eaten rare or without thorough cooking may use special labeling, including validated cooking instructions to support that trichinella is not reasonably likely to occur. This is at option three from the compliance guideline we talked about earlier.

With that, we'll be able to take any questions and if there are any questions that we don't address during the webinar, we do have our askFSIS website.

Melissa Hammar: Thank you, Dr. Silverman. We'd like to open the line now for any question.

Aasif, ATT Moderator: Ladies and gentlemen, as we move on to Q&A, please feel free to place yourself into the verbal question 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. As a reminder, you are also welcome to submit a written question. To do so, please use the chat panel on the lower right-hand side of your screen and then choose All Panelists from the send-to dropdown menu. Looks like we have received a question on the telephone line. That caller's line has been unmuted.

FSIS Webinar on Eliminating the Regulatory Requirements for Trichinella Spiralis in Pork Products.
~ July 17, 2018

Casey Gallimore: Hi. This is Casey Gallimore with the North American Meat Institute. I wanted to personally thank FSIS for hosting this webinar today. I think it's generally helpful and clarified some points of confusion with our members. Thank you. There was one thing that was a little bit new that I hadn't seen before. When talking about safe handling instructions being acceptable for fresh pork products, in all of the slides today, there's been a caveat put on that that only fresh pork products from confinement-raised swine, that was changed from the existing regulation until the effective date of the rule. In 318.10(a), there's no delineation between confinement-raised and non-confinement-raised swine. It simply states that all fresh pork products are acceptable because they are customarily well-cooked. Could you elaborate on the change?

Meryl Silverman: Okay. Yes. Thank you for your question, Casey. We do recognize that products from pasture-raised swine result in an increased risk of trichinella inspection. For that reason, we would expect that establishments would have additional support on file for a decision that trichinella is not reasonably likely to occur. You want to add anything to it?

Bill Shaw: No. I would say an establishment would want to acknowledge the difference in a scientific literature between those two types of swine raising processes and take that into account when making a hazard analysis decision.

Autumn Canaday: Caller, do you have another question?

Casey Gallimore: No. That's fine. Thank you.

Autumn Canaday: Okay. We have a written question. How will this proposal impact trading partners that export pork products to the U.S. and how will that change equivalency determinations?

Britney Brennick: This is Britney Brennick with the Export Policy Development Staff. As far as exports go, any country's specific changes will be updated - as far as letterhead certificate or the reference to the regulation that is being eliminated that are currently on the country's specific export library web pages - they will be updated accordingly and as necessary?

Melissa Hammar: I don't see how it would affect the equivalency. If another country wanted to try a different process, we would consider that. We may submit their SRTs.

Autumn Canaday: We also have another question that was just submitted. Canada is considered a trichinae free region. Would the agency accept this as justification in the HACCP plan?

Bill Shaw: Hi. This is Bill Shaw with the FSIS Office of Policy. Yes. If the establishment has technical information documenting that from the Canadian government. I'm sure that if there's a document prepared by the Canadian government

FSIS Webinar on Eliminating the Regulatory Requirements for Trichinella Spiralis in Pork Products.
~ July 17, 2018

that has supporting documentation of that situation, then they would file that as a supporting document and discuss that in the justification column in hazard analysis to support that decision.

Autumn Canada: Thank you. Do we have any calls on the line?

Aasif, ATT Moderator: As a reminder to those in the audience, if you'd like to ask a question over the phone, please press #2 on your telephone keypad. Otherwise, please submit a written question using the chat panel on the lower right-hand side of your screen. Let's give it a moment.

Once again, as a reminder, if you would like to ask a question, please press #2 on your telephone keypad. Otherwise, please use the chat panel on the lower right-hand side of your screen.

Meryl Silverman: Okay. Just a reminder that if there are further questions after the webinar, we have our askFSIS link up here and you're welcome to submit questions and we can provide an answer individually.

Autumn Canada: We have another question. Do all HACCP plans that process pork need to address the hazard as reasonably likely to occur (RLTO) or not reasonably likely to occur (NRLTO)?

Bill Shaw: Yes. This is Bill Shaw again. Yes, we would expect that. We would have expected that prior to July 30. I mean under the HACCP regulations of 417 and then also the previous prescriptive of 318.10, we would have expected establishments to have acknowledged and addressed trichinella one way or another in their hazard analysis. We would expect that establishments would not need to change that as of July 30. Trichinella is an established food safety hazard that has been associated with pork over the years since the HACCP rule was originally finalized in 1996. We wouldn't expect anything different to take place on July 30th from a hazard analysis point of view.

Meryl Silverman: Yes. Again, this is Meryl Silverman. Just to reiterate. For those products that have been under 318.10(a), those fresh raw, pork products, it could be a simple justification within the hazard analysis that the product bears safe handling instructions, and historical information shows those products are customarily well-cooked, and then there would be no need for following the options in the compliance guideline or a pre-requisite program or CCP.

Autumn Canada: Thanks, Dr. Silverman. We have another question. Does the NSF pork producing plant using validated cooking instructions to cook product to at least 145 degrees, need to do anything new in light of the content of the webinar?

Meryl Silverman: Yes. This is Meryl Silverman. For those cooking recommendations or requirements under the trichinae regulations, those same time

FSIS Webinar on Eliminating the Regulatory Requirements for Trichinella Spiralis in Pork Products.
~ July 17, 2018

temperatures have been moved within the compliance guideline. We would recommend if within the justification the support is the regulatory citation that establishment should update that to the compliance guideline since the regulation is going away but actually the limit and the monitoring procedures, those things would not need to change. It's just the supporting documentations for that time and temperature is now within the compliance guideline.

Bill Shaw: Yes. This is Bill again. If you look at our slide guideline, it's on page 14, which is the time and temperature table that we took exactly from 310.18 and moved it in to the compliance guide. All of those treatments that were in the CFR, we moved them into the guidance. They are still available. They're still available for establishments to use as supporting documentation and they're now housed in the compliance guide. I would say that same time temperature is accessible and is on page 14 of the compliance guide.

Autumn Canaday: Thank you. I have another question. With the increase in pasture-raised pigs, is there an expectation from FSIS that toxoplasmosis will be addressed in the hazard analysis?

Bill Shaw: Hi. This is Bill again. I think toxoplasmosis is an emerging issue that has been discussed by the Centers for Disease Control in their document. As we were developing the guidance, we felt that it was important to provide information to establishments because it's sort of what we do in guidance. We provide scientific information for people to consider. If you notice, it's sort of we're introducing it as something for people to know about. It's at the end of the guidance. It's about a page and a half. It gives just an overview of the organism. I think from our point of view, we have not set any policies around that. There's no expectation that establishments do any certain treatments or anything around that. We just wanted to make people aware that this organism exists. I think when conducting hazard analysis, folks should take into account various food safety hazards that may or may not impact their process. It's just an additional piece of information to consider.

Autumn: Thank you. Do we have any questions from the line?

Aasif, ATT Moderator: We did have one question on the phone line. That caller's line has been unmuted.

Autumn Canaday: Caller, go ahead.

Speaker 1: You just answered my question. I also sent it in written.

Autumn Canaday: Okay.

Speaker 1: Hello. Okay.

FSIS Webinar on Eliminating the Regulatory Requirements for Trichinella Spiralis in Pork Products.
~ July 17, 2018

Autumn Canaday: Yes. Thank you.

Speaker 1: Okay.

Autumn Canaday: There is another question. If purchasing pork from a supplier, how would one know if that is confinement or pasture-raised pork in order to address as a processing establishment?

Bill Shaw: Personally, I would expect that if an establishment is purchasing from a supplier, and they have subscribed their purchase justifications, and have had an interaction with that supplier as to what are the aspects of the product that they're purchasing, that a question should be asked as to how were these swine raised. I think, from my knowledge of the industry, it's a very important marketing situation. I would assume that establishments who are purchasing pork would ask that question whether it's confinement-raised or not. From my experience, there's a difference in price.

Autumn Canaday: We have a follow-up question on that. It's a very small plant purchased through a third-party distributor. Would you like to give more context on your question?

Bill Shaw: No. I mean I think what I'm understanding is probably a broker situation so they're purchasing product not from the original slaughter. I think it's still valuable information to ask the broker because in the marketplace there are different prices per pound versus different types of pork and how that pork was often raised. It is an important question to ask as to what type of product you're getting to ensure that you're making the best purchase decision. Yes. I mean you'll know base on talk because if it's significantly more profound then that's potentially pork that has a different raising process.

Autumn Canaday: Thank you. Aasif, do you have any calls on the line?

Aasif, ATT Moderator: Looks like we have no other questions in queue.

Autumn Canaday: Okay. There are no written questions at the moment. Again, if you have further questions, please feel free to reach out to askFSIS.

Aasif, ATT Moderator: As a reminder to audience, if you would like to ask a question, please press #2 on your telephone keypad to enter the verbal question queue. Otherwise, please submit a written question using the chat panel on the lower right-hand side of your screen. Let's give a moment.

Melissa Silverman: I want to thank everyone for participating today. Again, as a reminder, FSIS will make the recording and transcript for this webinar available on the Meetings and Events page on the FSIS website. Thank you again for participating and for listening. Hope you all have a great day.

FSIS Webinar on Eliminating the Regulatory Requirements for Trichinella Spiralis in Pork Products.
~ July 17, 2018

Aasif, ATT Moderator: Thank you all for joining today's call. The call is now concluded, and you may now disconnect.

[END OF TRANSCRIPT]