

July 13, 2018

Roberta Wagner
Assistant Administrator
Office of Policy and Program Development
Food Safety and Inspection Service
1400 Independence Ave. SW
Mailstop 3758, Room 6065
Washington, DC 20250-3700

Re: Final Rule; *Elimination of Trichinae Control Regulations and Consolidation of Thermally Process, Commercially Sterile Regulations*; Docket No. FSIS-2015-0036; 83 Fed. Reg. 25302 (May 30, 2018) and associated FSIS Compliance Guideline for the Prevention and Control of *Trichinella* and Other Parasitic Hazards in Pork Products.

Dear Ms. Wagner:

The North American Meat Institute (NAMI or the Meat Institute) submits these comments concerning the above-referenced final rule (the rule) eliminating trichinae control regulations and the associated compliance guideline (guidance). The Meat Institute has a rich, century-long history and provides essential member services including legislative, regulatory, scientific, international, and public affairs representation for the meat and poultry packing and processing industries. Together, NAMI members produce the vast majority of U.S. beef, pork, lamb, and poultry products in the United States.

NAMI's membership includes companies that slaughter various classes of swine. NAMI supports the Food Safety and Inspection Service's (FSIS or the agency) proposal to remove 9 CFR 318.10 (regulation) and to consolidate canned food regulations. FSIS's decision to remove the regulation is based on its inconsistency with Hazard Analysis and Critical Control Point (HACCP) regulations. The regulation is unnecessary, overly prescriptive, and prevents establishments from adopting alternate procedures to increase efficiency and improve the process. The proposal exhibits the agency's commitment to deregulation, as prescribed by Executive Order 13771.

Trichinae treatments prescribed in 9 CFR 318.10 are removed and relocated in the guidance as a safe harbor resource for establishments. The guidance, however, is troubling, especially concerning the agency's expectations regarding controls for fresh pork products. The guidance sets expectations for all pork establishments to assess whether trichinae is a hazard reasonably or not reasonably likely to occur in their process and implement a program to prevent or control trichinae. According to the guidance, many establishments that do not have trichinae treatment or control programs in place, such as those who produce fresh pork, will have to adopt one of the five options provided. Although the final rule claims it will impose no additional cost, each option is expensive to implement. After discussions with agency officials, the guidance does not reflect the agency's current policy thinking. Although the Meat Institute supports the rule, the agency should delay its effective date until the compliance guidance is revised.

Trichinae is no longer a hazard in all pork products.

The guidance provides trichinae is a known hazard in all ready-to-eat (RTE) and not ready-to-eat (NRTE) products. As such, an establishment must determine whether trichinae is reasonably likely to occur (RLTO) or not reasonably likely to occur (NRLTO) and trichinae must be addressed with either a critical control point (CCP) or prerequisite program (PRP), respectively.

The agency acknowledges the incidence rate of *Trichinella* infection in humans decreased significantly over the past 20 years, yet does not reconsider the previous assumption of trichinae as a known hazard in all pork products. The reduction in human infections mirrors the decreased prevalence of *Trichinella* infection in swine, especially confinement raised swine, since the regulation was promulgated in 1970. This reduction is attributed to improved husbandry practices, such as increased biosecurity, implementation of pest control management programs, and enhanced hygiene requirements. The agency also recognizes the significant decrease in trichinellosis due to good production practices and the biggest risk is in swine with access to rodents and wildlife.

From 1984 to 2012, over 43 million pigs were tested using the pooled sample digestion method under the Agricultural Marketing Service (AMS) slaughter testing program for exports, with no positive findings for *Trichinella* infection.¹ The risk of trichinellosis from U.S. commercial pork in the years between 2002 and 2007 was 1 in 285 million.² There were only two cases in the U.S. of trichinellosis from commercial pork from 2011 to 2016, one in 2012 and one in 2015.³ For those two

¹ National Pork Board Pork Safety Fact Sheet: *Trichinella*

² *Id.*

³ <https://www.cdc.gov/parasites/trichinellosis/data-statistics/tables.html>, 2016 data obtained from CDC National Outbreak Reporting System

years, the incident rate was at its highest, 0.003 per 1 million population.⁴ The data reflects *Trichinella* infection in the U.S. is rare.

In 1995, the National Advisory Committee on Microbiological Criteria for Foods (Committee) revised its HACCP document in response to the Codex Committee on Food Hygiene.⁵ HACCP, the internationally accepted food safety standard, employs 12 steps and seven principles. The first principle, conducting a hazard analysis, requires several preliminary steps, such as describing the food, its distribution, intended use, and consumers. The HACCP team should consider those aspects when determining hazards. The team should also consider the severity and likelihood of the hazard when determining whether it needs to be addressed. With the knowledge that fresh pork products are customarily well cooked by consumers⁶ and the prevalence of trichinellosis in the U.S. from commercial pork is extremely low, an establishment producing fresh pork products from commercial swine would likely not consider trichinae a hazard. The agency should amend the guidance to include the possibility that establishments may determine trichinae is not a hazard in their products.

Prerequisite programs are not necessary to support a hazard as NRLTO.

The guidance accurately explains establishments must implement a CCP for a hazard determined RLTO. The guidance also provides establishments may determine that trichinae is a hazard NRLTO in their products because of a prerequisite program. The agency offers no other suggestion for supporting trichinae is NRLTO. The implication that the only way an establishment may determine trichinae is NRLTO is by implementing a prerequisite program is false.

Establishments must provide supporting documentation for decisions in the hazard analysis, but the type of supporting documentation depends on the hazard, the establishment, and justification for the decision. Prerequisite programs are an option to support the conclusion a hazard is NRLTO. Other supporting documentation may be scientific evidence, letters of guarantee, following manufacturer recommendations, or plant history showing a low incident rate, depending on the hazard. The most common supporting documentation for trichinae as NRLTO in fresh pork products, and accepted for decades throughout U.S. establishments during countless Food Safety Assessments, is that fresh pork products are customarily well cooked. Yet this option was omitted in the guidance, implying it is no longer adequate justification. This option should be included in the guidance, which are supposed to represent best practices.

⁴ *Id.* Incident rate calculated using population estimates from the United States Census Bureau, World Bank

⁵ <https://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006801.htm>

⁶ 9 CFR 318.10(a)

The guidance establishes prerequisite program criteria inconsistent with regulation and previous policy decisions.

In accordance with 417.5(a)(1), establishments must maintain the written hazard analysis, including supporting documentation. The extent of the supporting documentation is not defined in regulation. The prerequisite program criteria provided on pages three and four of the guidance mirrors the criteria for critical control points.⁷ Previous policy decisions are best described by instructions found in directives or FSIS training.

The verification criteria used to assess prerequisite programs are different than the verification activities performed to verify HACCP system compliance. For prerequisite programs, inspection program personnel are to assess the overall effectiveness of the prerequisite program to verify that it continues to support the decisions made in the hazard analysis that foreign material contamination is not reasonably likely to occur in the process. Unlike with HACCP plans, inspection program personnel do not verify specific regulatory requirements for such activities as monitoring, verification, and recordkeeping.⁸

Prerequisite programs are outside the HACCP Plan but still within the HACCP System. The inspector **can not** apply the same criteria as they would verifying the regulatory requirements of the HACCP Plan. Inspection program personnel should evaluate prerequisite programs and determine if they continue to support the decision in the hazard analysis.⁹

The agency should remove the criteria from the guidance and replace it with a simple statement such as, “establishments must support the decision that trichinae is NRLTO.”

The guidance is unnecessarily prescriptive concerning options.

In the section “Options for Preventing and Controlling Trichinella in Pork Products,” establishments may use Option 1 or 2 if trichinae is determined NRLTO and Option 4 or 5 if trichinae is determined RLTO. Option 3 is not recommended anywhere in the section and its intended use is unclear. In the section “Control of Other Parasitic Hazards in Pork Products,” establishments may use Option 1, 2, or 3 if trichinae is determined NRLTO and Option 4 or 5 if trichinae is determined RLTO.

⁷ 9 CFR 417.2(c)

⁸ FSIS Directive 7310.5 *Presence of Foreign Material in Meat or Poultry Products*

⁹ https://www.fsis.usda.gov/wps/wcm/connect/19de69c2-8b28-45e7-8c3d-2a8252c1b75d/Training_Prerequisite_Programs.pdf?MOD=AJPERES

By creating expectations for which options to use for RLTO or NRLTO, a reverse expectation is created. For example, if a small establishment slaughters pasture raised swine and determines trichinae as RLTO, it may implement a testing program to ensure each carcass is trichinae free. In this scenario, the establishment has set testing as a CCP, but the guidance creates an expectation for testing to only be used as a prerequisite program. Establishments should have the flexibility to design their HACCP systems to best suit the facility, process, and products.

Guidance on food safety should not broach international standards.

Establishments that choose to export will need to ensure compliance with the importing country's requirements, which is separate from decisions made in the HACCP system. Although FSIS regulation and policy should not intentionally impede international trade, it is not appropriate to address trade in a guidance for a potential food safety hazard. FSIS should remove references to trade, the World Organisation for Animal Health (OIE), export, international requirements, and tracing product back to the farm of origin.

OPTION 1

The guidance retains the requirement for agency verification prior to product release.

The guidance states, "Tested pork or products made from tested pork **must** not be released as *Trichinella*-free from the official establishment without treatment until the IIC receives a laboratory report that the tested pork has tested negative for *Trichinella* (emphasis added)." Testing is no longer a regulatory requirement; therefore, verification by the IIC prior to release no longer makes sense. Testing will be incorporated into the HACCP system if used as support for a decision made in the hazard analysis. FSIS verification of trichinae testing programs should be conducted consistent with verification of the rest of the HACCP system, in accordance with Directives 5000.1 and 5000.6.

OPTION 2

The U.S. Trichinae Certification Program is not used.

The guidance claims to represent best practices, yet no companies are enrolled in the APHIS Trichinae Certification Program, the only program that meets the requirements of Option 2. The program is costly to producers, who do not benefit because they cannot charge a premium for hogs produced under the program. Packers have not required the program from their suppliers because it has not previously been an accepted method for trichinae prevention and does not qualify

product for export. The industry believes APHIS intends to eliminate the program due to lack of participation.

The Pork Quality Assurance (PQA) Plus Program is effective for trichinae prevention.

The rule states “the PQA Plus Program is an acceptable pre-requisite program for fresh pork products that were previously covered under 9 CFR 318.10(a),” yet it is not referenced in the guidance.¹⁰ FSIS should confirm in the guidance that sourcing swine from participants of the PQA Plus Program is an acceptable control for trichinae.

Testing products or carcasses from swine raised under a preharvest program is redundant and unnecessary.

Establishments that implement supplier approval programs requiring a preharvest pork safety program may decide to perform verification of supplier compliance through testing of carcasses or products. However, the guidance implies that all carcasses and products should be tested, negating the benefit of employing a preharvest program. The first sentence of the last paragraph on page six should be removed to prevent confusion.

OPTION 3

Product labeling options are unclear.

The guidance describes labeling requirements in addition to safe handling instructions (SHIs) to support trichinae as NRLTO in NRTE products. The note on page nine emphasizes SHIs cannot be used in lieu of the additional labeling requirements. It is unclear what products require the additional labeling requirements. Based on discussions with policy staff, the agency’s position is fresh pork products do not require treatment for trichinae because they are customarily well cooked by consumers and SHIs are sufficient to relay the need for proper cooking to consumers. However, the guidance states that establishments can use **special labeling** to support trichinae is NRLTO in NRTE products. The guidance does not provide a secondary option, implying special labeling is necessary and SHIs are not sufficient. The agency should clarify its position in the guidance. The Meat Institute suggests the agency take the position that SHIs are sufficient for fresh pork products and additional labeling may be used for product that might be eaten rare or without proper cooking.

On pages 4, 10, and 11 the guidance states establishments should treat NRTE pork products that might be eaten rare or without proper cooking because of the

¹⁰ 83 *Fed. Reg.* 25304

appearance of the product, yet the example label on page nine is for a smoked, cured pork sausage, which historically required treatment by the regulation. The guidance mirrors the regulation, stating that these type of products need to be treated for trichinae.¹¹ Special labeling is redundant if a product requires treatment. After discussion with agency personnel, the agency believes special labeling, in place of treatment, can support the conclusion that trichinae is NRLTO in NRTE pork products that might be eaten rare or without proper cooking, contrary to the regulation. The agency should clarify in Option 3 and on pages 4, 10, and 11 that establishments may use additional labeling to address trichinae in products that might be eaten rare or without proper cooking, instead of treatment. For improved readability, Option 3 should be broken into two parts: SHIs for products previously covered under 318.10(a) and special labeling for products previously covered under 318.10(b).

In addition, the information in the Key Question on page 11 should be moved up in the guidance to the section “*Options for Preventing and Controlling Trichinella in Pork Products.*” The explanation of which products are at greater risk is important for an establishment’s initial decision on which option to use and they may not read each option to find the explanation.

OPTION 4

It is unclear if the agency considers curing effective against trichinae.

The topic of whether processes for cured, dried, salt-cured, or fermented products are effective for destroying trichinae is discussed on pages 12, 14, 17, 30, and 31. The repetitive discussion is confusing and should be refrained to one section, preferably the “Special Consideration...” section on page 30. However, this section should be renamed, because the agency unintentionally calls the processes of freezing, high-pressure pasteurization, and irradiation into questions by referring to processes that do not rely on high temperatures. The section title should be shortened to “Special Consideration for Certain Processes to Control Trichinella in Pork”.

Throughout the numerous discussions, the agency’s position on these products becomes unclear. For example, the discussion in the green box on page 17 states all process currently approved for commercial use have been tested, includes a tangent on the definition of curing, and then says no curing process has shown to be effective. It seems an establishment would be required to implement a prevention or treatment step in addition to curing. The guidance should include a single discussion that clarifies processes included in the guidance (previously in the

¹¹ Guidance Page 11

regulation) are considered effective against trichinae. Establishments need to provide validation for processes not listed within the guidance.

OTHER PARASITES

The guidance establishes unprecedented expectations to address *Toxoplasma*.

The guidance was created in response to the removal of the regulation. The regulation does not pertain to *Toxoplasma*, yet the guidance does. The guidance states its purpose is to provide information on available options for the prevention and control of trichinae and other parasites, specifically *Toxoplasma*. On page 32, the guidance states that Options 1-3 may be used to prevent other parasites in the establishment's pork product, but Options 1 and 2 only pertain to trichinae. This leaves only two options: treatment or labeling. If the agency clarifies that SHIs are sufficient for fresh pork products that will prevent undue confusion and costly changes to establishments' HACCP Plans. However, the agency conveys limited information on the effects of curing on *Toxoplasma*, calling into question whether cured products will be expected to bear additional labeling or undergo further treatment. Either option will impose substantial costs to the establishment, which are not assessed by FSIS in the rulemaking process. The agency should clarify that the other parasite section is for informational purposes only and establishments may not determine *Toxoplasma* is a hazard at all.

There is a lack of data for toxoplasmosis attribution.

Toxoplasma cysts can remain viable in the body for a long period of time and reactivate in newly immunosuppressed people.¹² This delay makes accurate attribution unlikely. The CDC statement referenced in the guidance that *Toxoplasma* is the second leading cause of death due to foodborne illness is based on the total number of deaths from toxoplasmosis, not taking into account the source of the infection. Humans can contract a *Toxoplasma* infection from contamination through undercooked meat, drinking water, cat litter, and unwashed hands and vegetables from gardening. In a risk assessment, the greatest associated risk for *Toxoplasma* infection was cat ownership.¹³ In addition, as stated in the guidance, there is no available testing method for carcasses or products, so establishments are unable to assess prevalence. Categorization of a hazard is dependent on severity and likelihood. The lack of data on toxoplasmosis attribution to pork and the inability to test products makes likelihood unknown.

Miscellaneous Comments

¹² National Pork Board Pork Safety Fact Sheet: *Toxoplasma*

¹³ *Id.*

Page i: The second paragraph on the title page should be removed. It is redundant with the main content, confusing, and contradictory.

Page ii: The first paragraph is a great example of an introduction for agency guidance. Although there is always room to improve to ensure guidance is used appropriately, such as a disclaimer on each page of the document, the introduction is a welcome improvement from previous guidance.

Page ii: The first sentence in the second paragraph should be amended to read "...the requirements that RTE and **some** NRTE pork products be treated." Without a qualifier such as "some," the sentence implies that all pork products are required to be treated for trichinae under the regulation.

Page ii: The first and second sentences of the third paragraph are redundant and contradictory. The first says normal safe handling instructions (SHI) may be used; the second implies "special cooking instructions" are needed.

Page ii: The third sentence in the third paragraph implies a voluntary preharvest program is necessary for international trade of pork products, which is inaccurate. In addition, "suppliers" do not participate in international trade of pork products, establishments export products.

Page ii: The intent of the third paragraph is unclear. If intended to be a summary of the options listed in the guidance, it is missing the testing option, repeats the treatment and labeling options, and the discussion regarding the preharvest program option is too long.

Page 1: The data in the bottom left test box does not represent pork. There were 90 cases of trichinellosis reported to the CDC from 2008-2012, only 22 were attributed to pork products. Forty-one cases were attributed to bear meat. Six of the 22 pork cases were attributed to wild boar and one to home raised swine. In addition, the median is not a useful statistic when assessing prevalence. On average, there were three cases per year attributed to commercial pork from 2008 to 2012. From 2013 to 2016 the average dropped to 1.25.¹⁴

Page 2: Paragraph two states an APHIS-approved preharvest safety program is considered a prerequisite program. A preharvest program cannot be a prerequisite program because the establishment does not conduct the program. Instead, the agency should refer to a supplier approval program, where suppliers are required to participate in an APHIS approved preharvest program. The agency should also clarify that these programs **may** be used as prerequisite programs. The current wording implies that if a preharvest program is employed it is automatically a

¹⁴ <https://www.cdc.gov/parasites/trichinellosis/data-statistics/tables.html>, 2016 data obtained from CDC National Outbreak Reporting System

prerequisite program, rather than allowing the establishment flexibility in its HACCP system. For example, if an establishment has a supplier approval program to purchase swine from producers that participate in a preharvest program as a company requirement, but employs a treatment program for their products, the supplier approval program would likely not be a prerequisite program.

Page 2-3: The parenthetical note '(See "**Option 2: ...**")' implies either Option 2 is the only option that can be a prerequisite program or general information on how prerequisites function in the HACCP system will be provided in the section on Option 2, neither of which are accurate. The parenthetical note should be removed.

Page 4: Option 2 in the table should be reworded. Establishments purchase swine, not pork products, from producers.

Page 3: Option 3 in the table implies labeling beyond SHIs are required for fresh pork product unless Option 1, 2, 4, or 5 are employed; again making unclear the products Option 3 is intended to cover.

Page 5: The first full sentence states that the testing method is a prerequisite program. Again, the agency should clarify that these programs **may** be used as prerequisite programs. Testing may also be used as a verification method for another program. In addition, the testing method would likely not be a prerequisite, but rather the testing program.

Page 5: In the first full paragraph, FSIS should provide a reference for establishments to access instructions on how to perform trichinae testing.

Page 5: The second sentence in the second full paragraph should be reworded with the following suggested rephrasing: "Establishments should be aware that commercial test kits for antibodies are limited, because infectious cysts can be present before antibodies, which can take several weeks to develop after infestation of the live animal."

Page 5: Why must USDA certify establishments and laboratories that conduct trichinae testing? Establishments and laboratories can conduct pathogen testing or other testing that impact HACCP decisions and show competency in various ways such as third party certification and standardized methodology.

Page 8: The first sentence of the second paragraph should be revised, removing "*to control for Trichinella,*" from the end of the sentence. The statement is redundant and implies that labeling should include the reason along with the need for cooking.

Page 8: The label approval information provided in the second paragraph should be moved to the end of the section after the label example. Its presence in the middle of the paragraph is distracting and confusing.

Page 12: The note can be interpreted that all processes for dried, salt-cured, or fermented products must be validated. The agency should clarify that these products do not require process validation if the process is listed in Option 4, only validation that the establishment can achieve the parameters in the already validated process.

Page 31: The first full sentence states, “*An establishment must validate its process (i.e., either CCPs or prerequisite programs) used to eliminate Trichinella when it is determined to be RLTO.*” The parenthetical explanation should be removed. If an establishment determines a hazard as RLTO it must implement a CCP, therefore, prerequisite programs are not an option. The sentence is redundant and could be removed.

Page 33: The intent of the first sentence in the third full paragraph is unclear. There are no specific HACCP regulations for RTE products and the remainder of the paragraph refers to preharvest controls. The sentence is unnecessary, confusing, and should be removed.

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The removal of unnecessary and outdated regulations is appropriate and benefits all parties. However, the ramifications of their removal must be considered and accounted for in advance. Guidance materials are intended to reflect best practices and the agency’s current thinking on a topic. Based on discussions with agency personnel, this guidance does not reflect current policy thinking.

Thank you for the opportunity to provide these comments. The Meat Institute respectfully requests FSIS postpone the rule’s effective date until the guidance document is revised in response to these comments. Please contact me if you have questions concerning these comments or anything else regarding this matter. Thank you for your consideration.

Respectfully submitted,



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North American Meat Institute

Docket No. FSIS-2016-0017

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cc: Barry Carpenter
Mark Dopp