

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

7320.1
Revision 1

8/6/18

PREVENTION AND CONTROL OF TRICHINELLA IN PORK PRODUCTS

CHAPTER I - PREVENTION AND CONTROL OF TRICHINELLA IN DOMESTIC PORK PRODUCTS

I. PURPOSE

This directive provides inspection program personnel (IPP) with instructions on how to verify that establishments address *Trichinella* (*Trichinella spiralis*) during the production of pork products. FSIS is revising this directive because the Agency has removed the prescriptive regulatory requirements in 9 CFR 318.10 for the prevention and control of *Trichinella*. FSIS removed 9 CFR 318.10 because the regulations were inconsistent with the Hazard Analysis and Critical Control Point (HACCP) regulations (9 CFR part 417). Additionally, the previous version of this directive focused only on the treatment of sausage and sausage-like products for the destruction of *Trichinella*.

KEY POINTS:

- *Provides IPP instructions for verifying establishment's compliance with HACCP requirements when considering Trichinella in RTE and NRTE pork products*
- *Clarifies the available options that are effective for the prevention and control of Trichinella in RTE and NRTE pork products*
- *Provides IPP instructions for verifying fresh/frozen raw pork products for exports when produced under a pork quality plus program*

II. CANCELATION

FSIS Directive 7320.1, Treatment of Certain Meat and Poultry Products Containing Pork to Destroy Trichinae, dated 4/27/93.

III. BACKGROUND

A. On May 31, 2018, the Food Safety and Inspection Service (FSIS) published the final rule "Elimination of Trichinae Control Regulations and Consolidation of Thermally Processed, Commercially Sterile Regulations" ([83 FR 25302](#)). The final rule eliminated the prescriptive requirements in 9 CFR 318.10 for pork products to be treated to destroy *Trichinae* (*Trichinella*). FSIS removed 9 CFR 318.10 because the regulations were inconsistent with the HACCP regulations (9 CFR part 417). The HACCP regulations require establishments to consider food safety hazards in their hazard analysis (including *Trichinella*). FSIS anticipates that there will be little to no change for establishments as they were previously required to address *Trichinella* in their hazard analysis before the implementation of the final rule. The final rule became effective July 30, 2018.

DISTRIBUTION: Electronic

OPI: OPPD

B. The final rule requires establishments producing RTE and NRTE pork products to determine in their hazard analysis if *Trichinella* is a hazard reasonably likely to occur (RLTO) or not reasonably likely to occur (NRLTO) based on their processes. If *Trichinella* is a hazard that is RLTO, then establishments must include control procedures for this parasite in their HACCP plans, including the critical control points (CCPs) designed to control the parasitic hazard (9 CFR 417.2(c)(2)) and the critical limits that must be met at each CCP (9 CFR 417.2(c)(3)). Establishments are also required to maintain supporting documentation to justify the decisions made in their hazard analysis (9 CFR 417.5(a)(1)).

C. Under HACCP, most establishments may determine that *Trichinella* is NRLTO in fresh raw pork products produced from market swine because those products are customarily well-cooked and the products bear Safe Handling Instructions (SHIs). Examples of products that are customarily well-cooked include fresh pork (i.e., raw or uncured), fresh unsmoked sausage containing pork muscle, tissue, and bacon and jowls. All of these products were previously listed in 9 CFR 318.10(a).

NOTE: 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.

D. IPP are to be aware that there are certain other less commonly produced raw and NRTE pork products 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 prerequisite program or a CCP to support decisions in their hazard analysis. These other products include:

1. Pork products that are prepared in such a manner that the product might be eaten rare or without thorough cooking because the appearance of the finished product makes it hard for the consumer to visually determine if the product has been fully cooked. Such pork products include ground meat mixtures including those containing pork and beef as well as pork and other ingredients; poultry products containing pork muscle tissue; bacon wrapped products; breaded pork; raw marinated pork in dark sauces; pork products containing ingredients such as annatto, red wine, paprika, red pepper, etc. that can alter the appearance; cured pork; and cured and smoked pork. For these raw and NRTE products, one or more processing steps make it difficult for the consumer to visually determine whether the product has been fully cooked; and
2. Feral swine that have an increased risk of infection with *Trichinella*.

E. IPP are to be aware that for RTE pork products that achieve lethality by cooking, time/temperature/relative humidity combinations validated to achieve sufficient reductions in *Salmonella* (i.e., a 6.5- \log_{10} reduction) will also be effective at addressing *Trichinella*. However, for RTE pork products that achieve lethality by fermentation, salt-curing, and drying, because there are no published studies comparing the lethality rate of *Salmonella* to the destruction of *Trichinella*, establishments should not rely on procedures validated only for *Salmonella* to also address *Trichinella*.

F. To assist establishments in understanding the options that FSIS recommends for the effective prevention and control of *Trichinella* in the types of NRTE and RTE pork products described in D. and E. of this Section, the Agency developed a Compliance Guideline titled [FSIS Compliance Guideline for the Prevention and Control of Trichinella and Other Parasitic Hazards in Pork Products](#) (*Trichinella* Compliance Guideline).

G. The following Table summarizes the options recommended in the *Trichinella* Compliance Guideline:

List of Options used to Prevent and Control <i>Trichinella</i> in Pork and Products Containing Pork	
Option 1	Acquire pork products from carcasses or carcass parts found to be free of <i>Trichinella</i> by a validated testing method
Option 2	Obtain pork products from swine producers who participate in the Trichinae Certification Program or another APHIS-approved validated <i>Trichinella</i> preharvest safety program
Option 3	Label NRTE pork products, including all forms of fresh pork to indicate the products require additional treatment by the consumer
Option 4	Treat NRTE pork products for the destruction of <i>Trichinella</i> that might be eaten rare or without thorough cooking because of the appearance of the finished product using (1) heating, (2) freezing, (3) curing, (4) high pressure processing (HPP), or (5) irradiation
Option 5	Develop alternative <i>Trichinella</i> control procedures not included in Option 4

H. IPP are to be aware that establishments may follow any of the 5 options described in the table above including the option to use special labeling (Option 3) if they produce: 1) pork products that are prepared in such a manner that the product might be eaten rare or without thorough cooking because the appearance of the finished product makes it hard for the consumer to visually determine if the product has been fully cooked ; or 2) pork products from feral swine.

I. IPP are to be aware that FSIS' *Trichinella* Compliance Guideline represents best practice recommendations by FSIS, based on current scientific and practical considerations, and does not represent regulatory requirements that must be met. Establishments may choose to adopt different procedures than those outlined in the guideline, but they would need to support why or how those procedures are effective.

IV. IPP RESPONSIBILITIES

A. IPP in establishments that produce pork products are to notify establishment management of this directive at the next weekly meeting.

B. IPP are to inform the establishment that if it determined *Trichinella* is NRLTO and it produces pork products from market swine such as fresh pork, including fresh unsmoked sausage containing pork muscle tissue, and bacon and jowls that were previously listed in 9 CFR 318.10(a), it may support this decision with the justification that these products are customarily well-cooked and the products bear SHIs as described in Chapter I., Section III.C. of this directive.

C. IPP are to review the hazard analysis for the other types of pork and pork containing products described in Chapter I., Section III.D. and E. during the performance of either a routine HACCP verification task, in accordance with the instructions in [FSIS Directive 5000.1](#), *Verifying an Establishment Food Safety System*, or when conducting the HAV task, as described in [FSIS Directive 5000.6](#), *Performance of the Hazard Analysis Verification (HAV) Task*.

D. If IPP determine that the establishment has failed to support that *Trichinella* is prevented or eliminated in pork products described in Section III.D. and E. above, IPP are to initiate a regulatory control action in accordance with [9 CFR 500.2](#) and document the noncompliance by following the instructions in [FSIS Directive 5000.1](#) and [FSIS Directive 5000.6](#).

E. If IPP have questions regarding the adequacy of the support for the hazard analysis provided by an establishment, they are to seek guidance from their immediate supervisor or an Enforcement, Investigation, and Analysis Officer (EIAO) to determine whether there is a basis to question the adequacy of the support.

V. VERIFICATION INSTRUCTIONS FOR WHEN ESTABLISHMENTS USE SPECIAL LABELING (OPTION 3) IN LIEU OF OTHER OPTIONS TO SUPPORT THAT TRICHINELLA IS NRLTO

A. As explained in Section III.H., establishments may use special labeling including validated cooking instructions to support that *Trichinella* is NRLTO if they produce pork products: 1) that are prepared in such a manner that the product might be eaten rare or without thorough cooking because the appearance of the finished product makes it hard for the consumer to visually determine if the product has been fully cooked; or 2) from feral swine.

B. If an establishment is using special labeling, IPP are to perform the General Labeling task to verify that the official establishment maintains a copy of all labels used in accordance with parts [9 CFR 320.1\(a\)\(11\)](#) and [381.175\(b\)\(6\)](#), and that the following information is present on the immediate container:

1. A prominent statement on the principal display panel to indicate that the product is NRTE, for example, "Cook Thoroughly," or "Ready to Cook;"
2. Cooking instructions that result in a RTE product (e.g., "Cook to an internal temperature of 145 degrees Fahrenheit as measured by a food thermometer and allow to rest for 3 minutes before serving"); and

NOTE: If the minimum internal temperature above appears on the principal display panel, then the prominent statement in B.1 above may be omitted.

3. SHIs if the product is raw or the pork ingredient is NRTE.

NOTE: The labeling verification task discussed in this section of the directive is specific to products addressed in the *Trichinella* Compliance Guideline, in relation to the destruction of *Trichinella*.

C. If IPP determine that a product's special labeling does not contain all of the features outlined in the establishment's hazard analysis, then IPP are to conduct the appropriate HACCP task for the product category according to FSIS Directive 5000.1.

D. IPP are to be aware that if the establishment places a statement, such as "Cook thoroughly" on its label, the label may be generically approved in accordance with 9 CFR 412.2, unless the label falls under one of the four specific categories in 9 CFR 412.1 (labels for temporary approval; labels with deviations for export only; labels for religious exempt products; and labels with special statements or claims). To ensure that, in accordance with 9 CFR 317.8(a), the final labels are not false or misleading, IPP are to verify that the generically approved labels contain the information described in Section V.D. below.

E. An example label, along with the SHIs, is provided below.

Keep Frozen


Smoked, Cured Pork Sausage

INGREDIENTS: Pork, water, salt, sugar,
spices, and sodium nitrite

Distributed by: ABS Company, City, State, 12345

COOK THOROUGHLY

NET WEIGHT: 8 OZ







(Principal Display Panel)

Cook to an internal temperature of 145 degrees Fahrenheit as measured by a food thermometer and allow to rest for 3 minutes before serving.

Safe Handling Instructions

This product was prepared from inspected and passed meat and/or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions.

	Keep refrigerated or frozen. Thaw in refrigerator or microwave.
	Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat or poultry.
	Cook thoroughly.
	Keep hot foods hot. Refrigerate leftovers immediately or discard.

(Back Panel)

NOTE: The information in the SHIs cannot be used in lieu of the prominent statement described in B.1 or the cooking directions in B.2 above. These features need to be separate and distinct from the SHIs.

CHAPTER II - CERTIFYING FRESH/FROZEN RAW PORK PRODUCTS FOR EXPORT WHEN PRODUCED UNDER PORK QUALITY ASSURANCE PLUS (PQAPLus) PROGRAMS FOR TRICHINELLA MITIGATION

I. GENERAL

A. The Animal and Plant Health Inspection Service (APHIS) is implementing a new voluntary export program called the Pork Quality Assurance Plus Source Verification Program (PSVP). The PSVP requires slaughter, processing, and ID warehouse establishments to verify that pork products are sourced from swine farms that participate in the industry's National Pork Board's PQAPLus (NPB PQAPLus) program and that the pork products derived from these swine are identified, processed, and segregated from non-PQAPLus sourced pork products. Specific countries have agreed to accept pork and pork products certified for export by FSIS as free from *Trichinae* (*Trichinella*) when sourced, slaughtered, and produced in compliance with the APHIS PSVP or the Agricultural Marketing Service (AMS) PQAPLus Pork Export Verification (EV) program (AMS PQAPLus EV program).

B. Foreign countries often require a *Trichinella* mitigation processing step for raw pork and pork products and may require that cooked pork products be produced from pork that has also been subjected to a *Trichinella* mitigation to ensure the elimination of a *Trichinella* food safety hazard. FSIS has provided industry guidance for *Trichinella* mitigation processes in the *Trichinella* Compliance Guideline. When an importing country requires a *Trichinella* mitigation process, the mitigations found in the *Trichinella* Compliance Guideline can be implemented as specified in the importing country's Export Library to meet eligibility requirements.

C. Specific countries may accept pork imports without a *Trichinella* mitigation processing step based on the slaughter and processing establishment's participation in either the USDA APHIS PSVP or AMS PQAPLus EV programs. If the establishment participates in both programs, the establishment chooses which program to implement for each request for export certification. If specific countries accept pork imports based on FSIS certification under one USDA program but not the other, then the establishment must be an approved participant in the program required or accepted by the importing country.

D. Some establishments may also source swine or pork that is not eligible for export under the APHIS PSVP or AMS PQAPLus EV program. Identification and segregation of non-conforming from conforming products is a requirement to participate under either the APHIS or AMS program. Those non-conforming pork or pork products can still be eligible for export if one of the *Trichinella* mitigation processing steps noted in the *Trichinella* Compliance Guideline can be verified by IPP and are allowed by the importing country based on specific requirements found in the country's Export Library.

II. IPP RESPONSIBILITIES

A. IPP are to follow the instructions in [FSIS Directive 9000.1](#), *Export Certification* and FSIS Directive 9000.2, *Inspection and Export Certification of Livestock Intestines or Casings*, when certifying product for export.

B. Upon receiving FSIS Form 9060-6 Application for Export, IPP are to verify establishment and product eligibility from the information provided for the importing country in the Export Library. IPP are to request that the establishment produce the necessary documentation to show which *Trichinella* mitigation process was applied to the product or if it was produced in compliance with the APHIS PSVP or AMS PQAPLus EV program and that the conditions are being met to their satisfaction, as described in the applicable Export Library entry.

C. If the exporter is presenting the product as eligible under one of the two USDA programs, IPP are to check the Export Library to:

1. Determine if the product is eligible for export under the appropriate USDA program (i.e., either the APHIS PSVP or the AMS PQAPLus EV program); and
2. When the importing country allows pork and pork products to be certified for export under the [APHIS PSVP](#) or the [AMS PQAPLus Pork EV program](#), without additional mitigation processes, IPP are to:
 - a. Determine which USDA program the pork products have been produced under, either from the product identification or the applicant documentation;
 - b. Verify the establishment's eligibility by checking the [APHIS PSVP List of Participating Establishments](#) or the AMS [Official Listing for the PQAPLus Pork Export Verification Programs](#);
 - c. If the pork was purchased from a different source supplier for export, or for further processing before export, IPP are to verify that the source supplier is listed in the establishments Quality Systems Assessment (QSA) manual as an approved supplier; this provides verification that the product intended for export has been produced in compliance with the APHIS PSVP or AMS PQAPLus EV program as applicable; and
 - d. Verify that the product is eligible under the applicable program by using their e-authorization to log into the applicable [PartnerWeb](#) link database and verify that the product codes and product description match the information on the [FSIS Form 9060-6](#).

D. IPP are to have access to the establishment's written [APHIS PSVP](#) program or [AMS QSA](#) manual and associated records at all times upon request. These documents are to be kept at the establishment. If IPP are concerned that an establishment is not properly executing the approved APHIS PSVP or AMS PQAPLus Pork EV program, they are to:

1. Not issue or sign the FSIS Form 9060-5 Export Certificate of Wholesomeness for the consignment(s) in question and follow the instructions in [FSIS Directive 9000.1](#), document their observations in a Memorandum of Interview (MOI) issued to the establishment, and copy their supervisory chain;
2. Notify APHIS at ExportsProducts@aphis.usda.gov or AMS at QAD.AuditService@ams.usda.gov and provide the following information in the notification:
 - a. Establishment name, address, and number;
 - b. Product type, product code, and quantity of product;
 - c. Date of production, lot number, and shift;
 - d. Date and nature of observation;
 - e. Name of country for which product is intended;
 - f. Export certificate number (if applicable);

- g. Any other information to verify claim; and
 - h. Name of IPP documenting concerns.
3. Send a copy of the notification to their immediate FSIS supervisor and to ImportExport@fsis.usda.gov and maintain a copy of the message in the inspection office export file;
 4. Take the appropriate enforcement actions and issue a non-compliance record (NR) if any of the problems with the EV/QSA requirements are also a regulatory non-compliance; and
 5. Issue the establishment a MOI detailing the reason for refusing to sign the certificate as outlined in [FSIS Directive 9000.1](#).

E. If IPP believe the establishment is implementing their APHIS PSVP or AMS PQAPIus EV program as written, the product may be certified for export using the procedures outlined in [FSIS Directive 9000.1](#).

CHAPTER III – QUESTIONS

Refer HACCP questions regarding this directive through [askFSIS](#). When submitting a question through [askFSIS](#), use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter **Directive 7320.1**
 Question Field: Enter your question with as much detail as possible.

For **HACCP questions**:

Product Field: Select **PDS General** from the drop-down menu.
 Category Field: Select **HACCP** from the drop-down menu.
 Policy Arena: Select **Domestic (U.S.) only** from the drop-down menu.

For **Labeling questions**:

Product Field: Select **Labeling** from the drop-down menu.
 Category Field: Select **Labeling Regulations, Policies and Claims** from the drop-down menu.
 Policy Arena: Select **Domestic (U.S.) only** from the drop-down menu.

For **FSIS Compliance Guideline for the Prevention and Control of Trichinella and Other Parasitic Hazards in Pork Products questions**:

Product Field: Select **General Inspection Policy** from the drop-down menu.
 Category Field: Select **Sampling -General** from the drop-down menu.
 Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

For **Export questions**:

Product Field: Select **Exports** from the drop-down menu.
 Category Field: Select **Export Certificates** from the drop-down menu.
 Policy Arena: Select **International (Import/Export)** from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question**.

NOTE: Refer to [FSIS Directive 5620.1](#), *Using askFSIS*, for additional information on submitting questions.

A handwritten signature in black ink that reads "Sabrina J. Wagner". The signature is written in a cursive style with a large initial 'S'.

Assistant Administrator
Office of Policy and Program Development