

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

FSIS DIRECTIVE

7320.1
Revision 2

3/11/21

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 domestic pork products. This revised directive clarifies that there are no special instructions for feral swine, or products thereof. Since this directive addresses *Trichinella* during the production of domestic pork products, it eliminates the verification instructions specific to exports, which are included in Chapter II of [FSIS Directive 9000.1, Export Certification](#).

KEY POINTS:

- Provides IPP instructions for verifying establishment's compliance with Hazard Analysis and Critical Control Point (HACCP) requirements when considering *Trichinella* in Ready-to-Eat (RTE) and Not Ready-to-Eat (NRTE) pork products
- Clarifies that the inspection procedures for fresh pork products produced from feral swine are consistent with such products from confinement raised swine
- Clarifies the available options that are effective for the prevention and control of *Trichinella* in RTE and NRTE pork products

II. CANCELLATION

FSIS Directive 7320.1 Rev. 1, *Prevention and Control of Trichinella in Pork Products*, 06/08/18

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.

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

DISTRIBUTION: Electronic

OPI: OPPD

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. In the Final Rule and the Compliance Guideline titled [FSIS Compliance Guideline for the Prevention and Control of *Trichinella* and Other Parasitic Hazards in Pork Products](#) (*Trichinella* Compliance Guideline), FSIS explained that pasture-raised or feral swine are more likely than confinement-raised swine to be exposed to *Trichinella* and other parasites. However, FSIS does not have any special requirements unique to feral swine, or products thereof. As such, the compliance guideline recommends that establishments take this into consideration when conducting their hazard analysis. 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 Animal and Plant Health Inspection Service (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.

D. Therefore, most establishments may determine that *Trichinella* is NRLTO for raw pork products that are going to receive a thermal lethality 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.

E. IPP are to be aware that there are certain other less commonly produced raw and NRTE pork products from market swine 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: 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.

F. 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-log₁₀ reduction) will also be effective at addressing *Trichinella*. However, there are no published studies comparing the lethality rate of *Salmonella* to the destruction of *Trichinella* for RTE pork products that achieve lethality by fermentation, salt-curing, and drying. Therefore, establishments should not rely on procedures validated only for *Salmonella* to also address *Trichinella*.

G. 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 E. and F. of this Section, the Agency developed the *Trichinella* Compliance Guideline.

H. IPP are to be aware that establishments may follow any of the five options described in the table above including the option to use special labeling (Option 3) if they produce 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.

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 (i.e., confinement, pasture-raised, or feral) 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 Section III.D. of this directive.

C. IPP are to review the hazard analysis for the other types of pork and pork containing products described in Section III.E. and F. 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.E. and F. 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 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.

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.

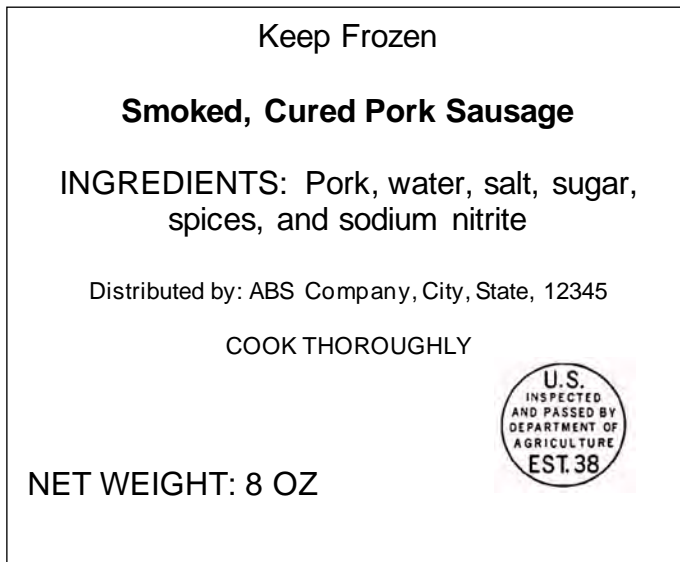
3. SHIs if the product is raw or the pork ingredient is NRTE.

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*.

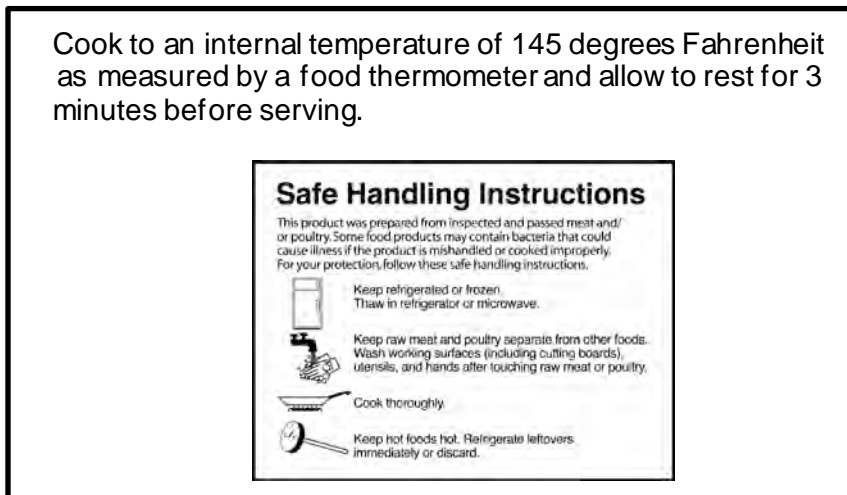
C. If IPP determine that a product's special labeling does not contain all of the features outlined in the establishment's hazard analysis, then IPP are to conduct the appropriate HACCP task for the product category according to [FSIS Directive 5000.1](#).

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.E.

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



(Principal Display Panel)



(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.

VI. QUESTIONS

Refer questions regarding this directive to the Office of Policy and Program Development through [askFSIS](#) and select **Sampling** as the Inquiry Type or by telephone at 1-800-233-3935.

Assistant Administrator
Office of Policy and Program Development