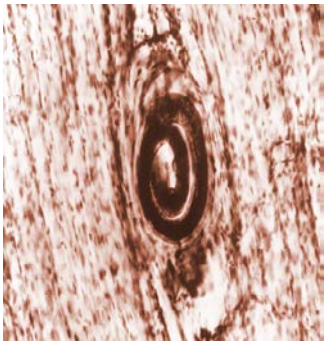
FSIS Compliance Guideline for the Prevention and Control of *Trichinella* and Other Parasitic Hazards in Pork Products

2018



This guideline is designed to help establishments, with a focus on small and very small establishments, understand available options that are effective for the prevention and control of *Trichinella spiralis* and other parasitic hazards in ready-to-eat (RTE) and not-ready-to-eat (NRTE) pork products.

Raw and NRTE pork products, including all forms of fresh (i.e., raw or uncured) pork, do not need to be treated to destroy *Trichinella* because they are customarily well-cooked in the home or elsewhere before being served to the consumer. An establishment may choose to label its product to control *Trichinella*.

Preface

What is the purpose of this compliance guideline?

FSIS developed this compliance guideline to assist establishments, particularly small and very small establishments, understand the available options that are effective for the prevention and control of *Trichinella spiralis* and other parasitic hazards, specifically, *Toxoplasma gondii*, in ready-to-eat (RTE) and not-ready-to-eat (NRTE) pork products. The guidance 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.

On 5/31/18, FSIS published the final rule "Elimination of Trichinae Control Regulations and Consolidation of Thermally Processed, Commercially Sterile Regulations" (83 FR 25302), which amends the Federal meat inspection regulations to eliminate the requirements that RTE and NRTE pork products be treated to destroy *Trichina* (*Trichinella spiralis*). FSIS removed these prescriptive regulations because they were inconsistent with the Hazard Analysis and Critical Control Point (HACCP) regulations, and are no longer necessary. Establishments now have the flexibility provided by the HACCP regulations (9 CFR Part 417) to develop appropriate science-based controls for *Trichinella* and other parasitic hazards in pork. All establishments producing pork products will have to determine whether *Trichinella* is a hazard reasonably likely to occur (RLTO) in their processes. If so, they will need to address this hazard in their HACCP system.

All establishments producing pork products will need to assess whether their products are to be treated for elimination of *Trichinella*, special cooking instructions are necessary on the label of the products, or safe handling instructions on labels are sufficient to ensure that the products are cooked to temperatures necessary to eliminate any live *Trichinella*. Establishments may decide to treat their products to address *Trichinella* or to include special cooking instructions on labels based on how consumers typically prepare the products or the likelihood that consumers will confuse the products with RTE products. Establishments may also make decisions based on whether their suppliers participate in international trade and a voluntary preharvest pork safety program, such as the Animal and Plant Health Inspection Service's (APHIS's) U.S. Trichinae Certification Program, or another APHIS-approved validated *Trichinella* preharvest safety program that complies with the World Organisation for Animal Health's (OIE's) guidance[1] for

[1] World Organisation for Animal Health Terrestrial Animal Health Code. Retrieved from http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_trichinella_spp.htm

Trichinella. OIE's guidance includes maintaining controlled management conditions for swine herds by functional separation using biosecurity measures, having two years of slaughter surveillance data to establish the compartment, auditing farms, and ensuring animal identification and traceability to the farm of origin. APHIS is working to develop standards for a program that would ensure that product for export comes from facilities that meet the international standards for *Trichinella*. These standards, once developed, may replace the U.S. Trichinae Certification Program.

This compliance guideline follows the procedures in the Office of Management and Budget's (OMB) "Final Bulletin for Agency Good Guidance Practices" (GGP). More information can be found on GGP on the Food Safety and Inspection Service (FSIS) webpage at: https://www.fsis.usda.gov/wps/portal/footer/policies-and-links/significant-guidance-documents/significant-guidance.

Who is this guideline designed for?

This guideline is designed for small and very small establishments in support of the Small Business Administration's initiative to provide compliance assistance under the Small Business Regulatory Enforcement Fairness Act (SBREFA). However, all FSIS regulated meat and poultry establishments may be able to apply the recommendations in this guideline. It is important that small and very small establishments have access to the scientific and technical support and assistance they need to establish safe and effective HACCP systems. Although large establishments can benefit from the guidance that FSIS provides, focusing the guidance on the needs of small and very small establishments provides these segments of the industry with information that may be otherwise unavailable to them.

What if I still have questions after I read this guideline?

If the desired information cannot be found within this compliance guideline, FSIS recommends that users search the publicly posted Questions & Answers (Q&As) in the askFSIS database or submit questions through askFSIS. Documenting these questions helps FSIS improve and refine present and future versions of the compliance guideline and associated issuances.

When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field:	Enter **FSIS Compliance Guideline for the Prevention and Control of *Trichinella* and Other Parasitic Hazards in Pork Products.**
Question Field:	Enter question with as much detail as possible.
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.

When all fields are complete, press **Continue**.

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

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

Background

Trichinella is a parasite that infects both humans and animals. Swine are the primary source of *Trichinella spiralis* infected meat that is ingested by humans (Hill et al., 2012). Humans can become infected with *Trichinella* by consuming encysted larvae in the muscle tissue of an infected animal. Trichinellosis in humans is caused by the consumption of raw or undercooked meat products containing *Trichinella* larvae.

The occurrence of *Trichinella* infection in humans due to the consumption of pork has decreased significantly in the U.S. over the past 20 years, although occasional sporadic outbreaks persist (Burke et al., 2008; Wilson et al., 2015). Much of this reduction is due to swine being raised in confinement. However, in organic, pasture raised swine that have access to rodents and wildlife infected with *Trichinella*, the risk of *Trichinella* infection to swine and subsequently humans are increased.

In the United States, trichinellosis cases are reported to CDC much less frequently now than in the past. During the late 1940s, when the U.S. Public Health Service began counting cases of trichinellosis, 400 cases in the U.S. were recorded each year on average. During 2008-2012, a median of 15 cases per year were reported to CDC. Over the past 40 years, few cases of trichinellosis have been reported in the U.S., and the risk of trichinellosis from commercially raised and properly prepared pork is very low. The overall number of cases reported has decreased because of improved swine-raising practices in the pork industry such as grain-fed swine being raised in confinement, commercial and home freezing of pork, and public awareness of the danger of eating raw or undercooked meat products.

KEY DEFINITIONS

Trichinella spiralis is a parasitic nematode (roundworm) which is found in many warm-blooded carnivores and omnivores, including swine. *Trichinella* is transmitted from one host to another host by ingestion of muscle tissue (meat) containing cysts (encysted larval stage of this parasite). Once the larvae encyst in the muscle tissue, they can remain alive and infective for years. The symptoms of trichinellosis often occur within 2 weeks after eating contaminated meat and can last up to 8 weeks. The classic symptoms of trichinellosis include: muscle pain; fever; swelling of the face, particularly the eyes; weakness or fatigue; headache; chills; itchy skin or rash; cough; diarrhea; and constipation.

Risk Comparing Swine Raised in Confinement Systems vs. Non-Confinement Systems

FSIS is aware that the risk of infection with *Trichinella* is increased in pasture raised swine that have access to rodents and wildlife infected with *Trichinella*. An increasing number of swine are being raised in non-confinement systems because of increased consumer demand for 'free-ranging,' 'organically raised,' and 'humanely raised' pork products (Hill et al., 2012; Honeyman et al., 2006). Feral swine are also reservoirs of infection with *Trichinella* for domestic swine reared in non-biosecure (or non-confinement) areas. Raising swine outdoors poses a major risk for swine of being infected with *Trichinella* because it increases exposure to potentially infected reservoir hosts (Hill et al., 2012; Gamble et al., 2000; Pyburn et al., 2005).

The risk of *Trichinella* infection in non-confinement swine can be substantially reduced by employing swine production practices that eliminate the sources of exposures to this parasitic hazard, thereby reducing the likelihood of human infection from consumption of pork infected with *Trichinella*. An establishment may determine in its hazard analysis that *Trichinella* is not reasonably likely to occur (NRLTO) in its products if the establishment gets its pork from swine producers who participate in an APHIS-approved validated *Trichinella* preharvest safety program; such programs are considered prerequisite programs. It is important for establishments to understand that such prerequisite programs designed to support a decision in their hazard analysis, are part of their overall HACCP system.

Because FSIS has removed the prescriptive Trichinae control regulations, establishments have greater flexibility to choose validated control procedures and to support their use as part of their HACCP system to control *Trichinella* and other parasitic hazards in pork products. Establishments producing RTE or NRTE pork products must assess in their hazard analysis if *Trichinella* and other parasites are hazards reasonably likely to occur (RLTO) or NRLTO in their processes. Establishments must include control procedures for these parasites in their HACCP plans if they determine that the parasites are a hazard that is RLTO, including critical control points (CCPs) designed to control the parasitic hazard [9 CFR 417.2(c)(2)] and critical limits that must be met at each CCP [9 CFR 417.2(c)(3)]. Establishments may determine that the parasitic hazard is NRLTO because a prerequisite program prevents the hazard, but they must have documentation to support the decisions in their hazard analysis [9 CFR 417.5(a)(1)]. The options for preventing and controlling *Trichinella* in pork products are described in the section "**Options for Preventing and Controlling *Trichinella* in Pork.**"

When an establishment determines that a hazard, such as *Trichinella*, is NRLTO because the prerequisite program prevents the hazard, then that prerequisite program becomes part of the HACCP system. (See **"Option 2: Obtain Pork Products from**

Swine Producers who Participate in the Trichinae Certification Program or another APHIS-approved validated *Trichinella* preharvest safety program" for more information.)

Options for Preventing and Controlling *Trichinella* in Pork Products

Under HACCP regulations, establishments are required to conduct a hazard analysis to determine the food safety hazards that are RLTO in their production processes, in accordance with 9 CFR 417.2(a)(1). Establishments must list the CCPs designed to control hazards identified as RLTO [9 CFR 417.2(c)(2)] and establish critical limits that must be met [9 CFR 417.2(c)(3)]. Establishments are also required to maintain documentation that supports the decisions made in their hazard analysis as a part of their records under 9 CFR 417.5(a)(1).

If establishments determine in their hazard analysis that *Trichinella* is a hazard RLTO, then they need to implement a CCP to eliminate the hazard. FSIS recommends that establishments use one of the following treatment methods described in **Option 4** to control *Trichinella* in their pork products: 1) heating, 2) freezing, 3) curing, 4) high pressure processing (HPP), or 5) irradiation. Establishments will need to be specific in their HACCP plans as to which treatment method they are using, and the critical parameters being measured [9 CFR 417.5(a)(2) and 417.2(c)(3)]. Establishments will also need to validate the selected method [9 CFR 417.4(a)(1)] by demonstrating that they are able to consistently meet the specific parameters outlined in the selected treatment method. Establishments may also develop alternative *Trichinella* control procedures, as described in **Option 5**.

As part of the hazard analysis, establishments may determine that *Trichinella* is a hazard NRLTO in their products because of the implementation of a prerequisite program. If an establishment decides to prevent *Trichinella* in their pork product(s) by implementing a prerequisite program, then it must keep documentation that supports the decisions made in its hazard analysis as a part of its records [9 CFR 417.5(a)(1)]. Additionally, the prerequisite program should meet the following criteria:

1. Written and describes procedures that the establishment will implement to show the hazard is NRLTO;
2. Designed to prevent the hazard from being RLTO, and the establishment maintains supporting documentation that the program has been validated (i.e., scientific or technical support and in-plant validation data);
3. Describes records that the establishment will keep demonstrating that the program is being implemented as written;

4. Describes records the establishment will keep to demonstrate that the program effectively prevents the hazard (i.e., on-going verification of the decision that the hazard is NRLTO); and
5. Describes actions the establishment will take when it fails to implement the program, or when it finds the program has failed to prevent the hazard (i.e., corrective actions in response to an unforeseen hazard as per 9 CFR 417.3(b) and as per 9 CFR 416.15 if the program is a Sanitation SOP).

If the design of the prerequisite program is not consistent with the criteria described above, then the establishment likely has not met the requirements of 9 CFR 417.5(a)(1).

The following prerequisite programs, as further described in **Options 1-2**, may be used by establishments to prevent *Trichinella* in their pork products: 1) acquire pork products from carcasses or carcass parts found to be free of *Trichinella* by a validated testing method; or 2) obtain pork products from swine producers who participate in the Trichinae Certification Program or another APHIS-approved validated *Trichinella* preharvest safety program.

List of Options used to Prevent and Control *Trichinella* in Pork and Products Containing Pork	
Option 1:	Acquire pork products from carcasses or carcass parts found to be free of *Trichinella* post-slaughter 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 *Trichinella* preharvest safety program
Option 3:	Label NRTE pork products, including all forms of fresh pork to clearly indicate the products require additional treatment by the consumer
Option 4:	Treat NRTE pork products for the destruction of *Trichinella* that might be eaten rare or without thorough cooking because of the appearance of the finished product
Option 5:	Develop alternative *Trichinella* control procedures not included in Option 4

Option 1: Acquire pork products from carcasses or carcass parts found to be free of *Trichinella* by a validated testing method

Pork products from carcasses or carcass parts that have been found to be free of *Trichinella* by a validated post-slaughter testing method are not required to be treated for

the destruction of *Trichinella.* The validated testing method is a prerequisite program, and establishments may determine that *Trichinella* is NRLTO if their product has been found to be free of *Trichinella* through post-slaughter testing using a validated method.

Testing must be performed using a validated method that is equivalent to or better than the tissue digestion assay method for detecting *Trichinella* in pork (known as the Magnetic Stirrer Method for Pooled Sample Digestion), using a 5-gram sample of tongue, muscles of the face (e.g., masseter muscle), diaphragm muscles, or neck muscles. A 5-gram sample of diaphragm, foreleg, or tongue should be used for non-confinement raised swine (e.g., feral swine, pasture-raised swine, free-ranging swine).

Any process-verification testing should be performed using a validated testing method that is equivalent to or better than the digestion assay method for detecting *Trichinella* in pork. Processors should be aware of the limitations of the readily available commercial test kits that test for antibodies that may not show up for several weeks following infestation. Such test results are not acceptable or equivalent to tissue digestion methods to rule out the presence of trichinae in meat product.

If establishments select Option 1 to control *Trichinella* in pork and products containing pork, they should be aware of the following:

- The establishment must keep on file and make available to FSIS inspection program personnel (IPP) its procedure for testing, to include identifying and pooling carcasses, collecting and pooling samples, testing samples, communicating test results, retesting individual carcasses, and maintaining positive identification and clear separation of pork found to be *Trichinella*-free by testing from untested pork or *Trichinella*-positive pork.

- The establishment may test in-house or may contract for testing by a private testing laboratory. Personnel conducting the testing for *Trichinella* must be certified to perform the validated testing method, and laboratories where testing is performed must be certified for *Trichinella* testing. Certifications are obtained by participation in a USDA *Trichinella* testing program such as the Agricultural Marketing Service (AMS) Trichinae Analyst Program or other FSIS approved certification programs. Certification must be based on adequacy of facilities, reagents, and equipment and on demonstration of continuing competency and reliability of personnel performing the validated testing method for *Trichinella*. A certificate is provided to the establishment's analyst (i.e., the personnel certified to perform the validated testing method) and laboratory manager, and the FSIS Inspector-in-Charge (IIC) as evidence of certification. Private testing laboratories would provide certification documentation to their customer.

- Sampling and sample preparation are subject to inspection by FSIS.

- 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*.

Option 2: Obtain pork products from swine producers who participate in the Trichinae Certification Program or another APHIS-approved validated *Trichinella* preharvest safety program

Establishments may determine that *Trichinella* is NRLTO in their products if they obtain pork from swine producers that participate in the U.S. Trichinae Certification Program (9 CFR Part 149), which is a prerequisite program for *Trichinella*. This is a voluntary preharvest pork safety program in which APHIS certifies pork production sites that follow all the required good production practices (GPPs) that reduce, eliminate, or avoid the risk of exposure of swine from their sites to *Trichinella*. In the U.S. Trichinae Certification Program, adherence to the GPPs is verified by periodic site audits conducted by APHIS. Establishments are also required to maintain documentation that supports the decisions made in their hazard analysis for this prerequisite program as a part of their records under 9 CFR 417.5(a)(1). The key GPPs components for the U.S. Trichinae Certification Program include:

- Feed integrity, source and storage.
- Building construction and condition as it pertains to biosecurity (i.e., swine raised in confinement).
- Integrity of rodent control programs.
  - Prevent exposure to rodents or other wildlife infected with *Trichinella*. Rodents can serve as a reservoir host for *Trichinella*.
- General management and hygiene issues as they pertain to rodent control, cannibalism and other issues.
  - Prevent cannibalism among swine within an infected herd.
  - Boots worn solely in confinement facility.

Pork products from carcasses or carcass parts from swine herds that have been raised by producers that follow these GPPs, and thus are certified under the U.S. Trichinae Certification Program, should still be tested at slaughter to verify that the adherence to good manufacturing practices and GPPs is resulting in the absence of *Trichinella* infection in swine from that herd. It is recommended that the slaughter facility that is processing certified swine perform process-verification testing to determine the *Trichinella* infection status of certified swine under its control. Process-verification testing should be performed using a validated testing method that is equivalent to or better than the tissue digestion assay method for detecting *Trichinella* in pork, described in **Option 1**.

It is important for establishments to understand that pork products originating from *Trichinella*-free certified swine is certified pork, and these products are not required to be treated for the destruction of *Trichinella*.

Establishments may also determine that *Trichinella* is NRLTO in their products if they obtain pork from swine producers that participate in an APHIS-approved validated *Trichinella* preharvest safety program that is in compliance with OIE's guidance for *Trichinella*. Participation in such a program would be a voluntary preharvest pork safety program. As a part of the record keeping required under 9 CFR 417.5(a)(1), participating establishments would need to maintain documentation to support the decisions made in their hazard analysis for this prerequisite program. Establishments would also need to have the ability to trace product back to the farm of origin.

International requirements for *Trichinella* include the ability to trace product back to the farm of origin, an audit process to ensure compliance, slaughter surveillance, and adherence to GPPs that include:

- Ensuring the integrity of rodent and other wildlife control and mitigation programs.
    - Prevent swine exposure to rodents or other wildlife infected with *Trichinella*. Rodents can serve as a reservoir host for *Trichinella*.
- Ensuring the integrity of the feed source and feed storage.
    - Raw food waste of animal origin is not present on the farm and is not fed to pigs.
    - Feed is not exposed to rodents or other wildlife potentially infected with *Trichinella*.
- Practicing good general management and hygiene.
    - Prevent cannibalism among swine within a herd.
- Sourcing swine.
    - Pigs originate from herds officially recognized as participating in an APHIS-approved preharvest safety program for *Trichinella* that meets international standards.

It is important for establishments to understand that pork products originating from swine produced in facilities that meet the standards of an APHIS-approved validated *Trichinella* preharvest safety program are not required to be treated for the destruction of *Trichinella.* However, it is recommended that the slaughter facility that is processing swine perform process-verification testing to determine the *Trichinella* infection status of swine under its control.

Option 3: Label NRTE pork products, including all forms of fresh pork to clearly indicate the products require additional treatment by the consumer

Establishments must decide in their hazard analysis whether *Trichinella* is NRLTO or RLTO in their production process. To support in their hazard analysis that *Trichinella* is NRLTO in their NRTE pork products, establishments can use special labeling of products to require additional treatment by the consumer. NRTE pork products, including all forms of fresh (i.e., raw or uncured) pork, do not need to be treated to destroy *Trichinella* because they are customarily well-cooked in the home or elsewhere before being served to the consumer.

If an establishment chooses to label its product to control *Trichinella*, then it should label the product so that the consumer understands that the product is raw or NRTE and needs to be fully cooked to control for *Trichinella*. The use of labeling may be generically approved by FSIS's Labeling and Program Development Staff (LPDS) in accordance with 9 CFR 412.2, unless the establishment adds a claim to the label or takes some other action that would render the label ineligible for generic approval. If the establishment has a generically approved label, it would not be necessary to subject that product to treatment for *Trichinella* if the product's label clearly indicates the raw or NRTE nature of the product and provides consumers with the following adequate food safety information:

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 #1 above may be omitted.

3. Safe handling instructions (SHIs) if the product is raw or the pork ingredient is not RTE.

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

U.S. INSPECTED AND PASSED BY DEPARTMENT OF AGRICULTURE EST. 38

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

(Back Panel)

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

Establishments can submit labeling questions to the LPDS through askFSIS. LPDS can also be reached by telephone at 1-800-233-3935.

When submitting a labeling question through askFSIS, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field: Enter **FSIS Compliance Guideline for the Prevention and Control of *Trichinella* and Other Parasitic Hazards in Pork Products.**

Question Field: Enter your question with as much detail as possible.

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.

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

Option 4: Treat NRTE pork products for the destruction of *Trichinella* that might be eaten rare or without thorough cooking because of the appearance of the finished product

Establishments that determine in their hazard analysis that *Trichinella* is a hazard RLTO need to employ process controls to eliminate the hazard.

Pork products need to be treated for the destruction of *Trichinella* if they are to be prepared in such a manner that the product might be eaten rare or without thorough cooking because of the appearance of the finished product. Some ingredients (e.g., annatto, red wine, paprika, red pepper, etc.) may also alter the appearance of the finished product, making it difficult for the consumer to visually determine whether the product has been fully cooked.

Certain pork products that require treatment for the destruction of *Trichinella* are mixtures of pork with other meats and poultry; bacon wrapped products; breaded pork; raw marinated pork in dark sauces; colored pork; cured pork; and cured and smoked pork. For these products, one or more processing steps make it difficult for the consumer to visually determine whether the product has been fully cooked, such as encasing the raw pork or coloring the raw pork.

NOTE: Poultry products containing pork muscle tissue are also required to be treated for the destruction of *Trichinella* in accordance with 9 CFR 424.21(a)(3)(iii).

KEY QUESTION

Question: Are certain pork products, such as pork cuts, pork sausage, and bacon, required to be treated for the destruction of *Trichinella*?

Answer: No. Certain pork products, including fresh unsmoked sausage containing pork muscle tissue, and pork such as bacon and jowls are classed as products that are customarily well cooked in the home or elsewhere before being served to the consumer. Therefore, these products are not required to be treated to destroy *Trichinella*.

As described in "**Option 4**," pork products need to be treated for the destruction of *Trichinella* if they are prepared in such a manner that the product might be eaten rare or without thorough cooking because of the appearance of the finished product. Additionally, certain products requiring treatment for the destruction of *Trichinella* are mixtures of pork with other meats and poultry; bacon wrapped products; breaded pork; raw marinated pork in dark sauces; colored pork; cured pork; and cured and smoked pork. For these products, one or more processing steps make it difficult for the consumer to visually determine whether the product has been fully cooked, such as encasing the raw pork or coloring the raw pork. Also, poultry products containing pork muscle tissue are required to be treated for the destruction of *Trichinella* in accordance with the requirements addressed in 9 CFR 424.21(a)(3)(iii).

As previously discussed, establishments must determine in their hazard analysis whether *Trichinella* is a hazard RLTO in their production processes [9 CFR 417.2(a)(1)]. If so, then establishments must list the CCPs designed to control *Trichinella* [9 CFR 417.2(c)(2)] and the critical limits that must be met at each of the CCPs [9 CFR 417.2(c)(3)]. Also, establishments must keep documentation that supports the decisions made in their hazard analysis as a part of their records [9 CFR 417.5(a)(1)]. Further, establishments are also required to validate the selected method, in this case to control the *Trichinella* hazard, as per 9 CFR 417.4(a)(1), by demonstrating that they are able to consistently meet the specific parameters outlined in the selected treatment method.

If *Trichinella* has been determined to be RLTO, then the establishment may elect to use one of the following treatment methods to destroy the parasite in its pork products: 1) heating, 2) freezing, 3) curing, 4) HPP, or 5) irradiation. As an example, an establishment may use the freezing treatment method as a CCP in its HACCP plan to eliminate *Trichinella* in its pork product where the thickness of the meat or inside dimensions of the container does not exceed 6 inches (i.e., Group 1 products – see **Table 2**). The critical limits for Group 1 products would be a continuous temperature no higher than 5°F for 20 days.

FSIS considers these methods, when properly applied and validated, to be sufficient to destroy *Trichinella*. Establishments can also elect to develop alternative treatments for the destruction of *Trichinella*, as described in **Option 5**.

NOTE: If an establishment is producing RTE pork products, then compliance with the lethality performance standards for the reduction of *Salmonella* will ensure the elimination of *Trichinella* because the time/temperature combinations for *Salmonella* are higher than the heat treatment for *Trichinella*. However, because there are no published studies comparing the lethality rate of *Salmonella* to the destruction of *Trichinella* in dried, salt-cured, or fermented products, FSIS cannot state with absolute certainty that the lethality performance standards for *Salmonella* in these types of products would also eliminate *Trichinella.* Therefore, if an establishment identifies *Trichinella* as a hazard that is RLTO, then the establishment will have to ensure that the process is validated and verified to effectively eliminate *Trichinella*.

Critical Operational Parameters for the Methods used for the Destruction of *Trichinella* in Pork

Critical operational parameters are the specific conditions that the intervention must operate under for it to be effective. The interventions, or methods, used to eliminate *Trichinella* from pork products include heating, freezing, curing, HPP, or irradiation. The critical operational parameters important for each treatment method are listed and described below.

Time/temperature combination

It is important that the time and temperature combinations adhere to the specific parameters described in **"HEATING," "FREEZING,"** and **"CURING."** The specific time-temperature parameters apply only when the product reaches and maintains temperatures evenly distributed throughout the meat. Alternative methods of heating, particularly the use of microwaves, have been shown to give variable results, with parasites not completely inactivated when product was heated to reach a prescribed end-point temperature. Establishments must maintain on file the recording of actual times and temperatures as specified in their HACCP plans, 9 CFR 417.5(a)(3).

Product, including product in containers, undergoing refrigeration must be spaced in such a way to ensure a free circulation of air between the pieces of meat, layers, blocks, barrels, and tierces for the desired temperature of the meat to be promptly and uniformly reduced.

Equipment settings or calibrations

In accordance with 9 CFR 417.4(a)(2), establishments are required to calibrate process-monitoring instruments as part of ongoing verification activities and are required to

support their verification procedures and the frequencies of those procedures. Further, establishments must have records on file documenting the calibration of process-monitoring instruments, 9 CFR 417.5(a)(3).

The smokehouses, drying rooms, and other compartments used in the treatment of pork must be appropriately equipped with accurate automatic recording thermometers to ensure that temperatures that effectively eliminate *Trichinella* are maintained. Automatic recording thermometers and the thermometers used must be calibrated periodically (frequency determined as per HACCP plan) to ensure that they are functioning accurately.

Pressure

HPP is an antimicrobial treatment that exposes the product to elevated pressures, with or without the addition of heat, to inactivate *Trichinella*. Pork processed with HPP is placed in a sealed flexible container. The flexible container is placed in a basket or barrel and moved to a high-pressure chamber filled with a pressure-transmitting fluid, usually water, which does not contact product. The chamber is equipped with pumping and decompression systems. The action of the high pressure causes inactivation of *Trichinella* larvae. Establishments must follow the specific parameters in **"HIGH PRESSURE PROCESSING"** for eliminating *Trichinella* in pork.

Irradiation

The type of radiation used in irradiating food is ionizing radiation, which includes high energy gamma rays, X-rays and accelerated electrons. For *Trichinella,* the process involves exposing the food product to carefully controlled amounts of ionizing radiation for a specific time to destroy the parasite. Ionizing radiation does not increase the normal radioactivity level of the food, regardless of how long the food is exposed to the radiation, or how much of an energy dose is absorbed. The types of ionizing radiation include gamma rays (from radioactive isotopes cobalt-60 or cesium-137), beta rays generated by electron beam or "E-beam," and X-rays (ICGFI, 1999; Smith et al., 2004).

The amount of ionizing radiation that is absorbed by the food product is called the radiation absorbed dose. Ionizing radiation is measured in units of rads (1 rad=100 erg/g) or grays (1 Gy=100 rads), with 1,000 grays equal to 1 kiloGray (kGy) (ICGFI, 1999; Smith et al., 2004). The doses used to eliminate parasitic hazards in pork are listed in **"IRRADIATION."**

HEATING

Heat is an effective method that is used to destroy *Trichinella* in pork products. If the steps described below are followed, FSIS considers the resulting product safe from *Trichinella*. The heating method is unnecessary if an establishment is producing RTE

products containing pork in compliance with the higher lethality performance standards for *Salmonella*. However, FSIS cannot state with absolute certainty that the lethality performance standards designed to reduce *Salmonella* for dried, salt-cured, or fermented products will eliminate *Trichinella.* Therefore, establishments will have to ensure the lethality process used for these types of products effectively eliminates *Trichinella*.

Table 1 - Time and Temperature Combinations to Eliminate *Trichinella*

Minimum internal temperature		**Minimum time**
Degrees F	**Degrees C**	
120	49.0	21 hours
122	50.0	9.5 hours
124	51.1	4.5 hours
126	52.2	2.0 hours
128	53.4	1.0 hour
130	54.5	30 minutes
132	55.6	15 minutes
134	56.7	6 minutes
136	57.8	3 minutes
138	58.9	2 minutes
140	60.0	1 minute
142	61.1	1 minute
144	62.2	Instant

1. All parts of the pork muscle tissue should be heated according to one of the time-temperature combinations in the above table to eliminate *Trichinella*.

2. Time and temperature must be monitored using a calibrated device that meets the requirements provided in "**General Instructions for Recording Thermometers**" at the end of this section.

3. Time, in combination with temperatures of 138°F to 143°F, need not be monitored if the product's minimum thickness exceeds 2 inches (5.1 cm), and refrigeration of the product does not begin within 5 minutes of attaining 138°F.

4. The establishment should use procedures that ensure the uniform heating of the product. It is important that each piece of sausage, each ham, and other product treated by heating in water be kept entirely submerged throughout the heating period. The establishment must ensure the largest pieces in a lot, the innermost links of bunched sausage or other massed articles and pieces placed in the coolest part of a heating cabinet or compartment or vat, be included in the temperature tests.

FREEZING

Trichinella is susceptible to prolonged periods of cold temperatures. If one of the following procedures is followed, FSIS considers the resulting product safe from *Trichinella*.

At any stage of preparation and after preparatory chilling to a temperature of no more than 40°F or preparatory freezing, all parts of the muscle tissue of pork or product containing such tissue should be subjected continuously to a temperature no more than one of those specified in Table 2. The duration of such freezing at the specified temperature is dependent on the thickness of the meat or inside dimensions of the container.

Table 2 - Required Period of Freezing at Temperature Indicated

Temperature °F	Group 1 Products (Days)	Group 2 Products (Days)
5	20	30
-10	10	20
-20	6	12

1. Group 1 comprises product in separate pieces not exceeding 6 inches in thickness, or arranged on separate racks with the layers not exceeding 6 inches in depth, or stored in crates or boxes not exceeding 6 inches in depth, or stored as solidly frozen blocks not exceeding 6 inches in thickness.

2. Group 2 comprises product in pieces or layers, the thickness of which exceeds 6 inches but not 27 inches. When the product is placed in containers, including tierces, barrels, kegs, and cartons, the containers do not exceed 27 inches in depth. Thus, the product will receive the effects of the refrigeration/freezing throughout its entire mass in the timeframes specified.

3. The product, including in containers, undergoing such refrigeration must be spaced in such a way in the freezer as to ensure a free circulation of air between the pieces of meat, layers, blocks, boxes, barrels, and tierces so that the desired temperature of the meat will be promptly and uniformly reduced to no higher than 5°F, -10°F, or -20°F, as respectively per product group.

4. As an alternative to the methods prescribed in Table 2, the treatment may consist of commercial freeze-drying or controlled freezing, at the center of the meat pieces, in accordance with the times and temperatures specified in Table 2A.

Note: To control for *Trichinella* in whole pork carcasses, the product needs to be frozen solid.

Table 2A - Alternate Periods of Freezing at Temperatures Indicated

Maximum internal temperature		Minimum Time
Degrees F	**Degrees C**	
0	-17.8	106 hours
-5	-20.6	82 hours
-10	-23.3	63 hours
-15	-26.1	48 hours
-20	-28.9	35 hours
-25	-31.7	22 hours
-30	-34.5	8 hours
-35	-37.2	1/2 hour

5. During the period of freezing, the product should be stored in the rooms or compartments where the lots can be controlled and not comingled so that the product does not leave the rooms or compartments until it is fully treated. The rooms or compartments containing product undergoing freezing need to be equipped with accurate thermometers placed at or above the highest level at which the product undergoing treatment is stored and away from refrigerating coils.

6. Pork product that has been frozen needs to be controlled in such a way as to ensure that the treated product is designated and not comingled with untreated product.

CURING

Curing is another method recognized for the control of *Trichinella*. The curing methods described below are effective for destroying *Trichinella* in sausage, capocollo, coppa, hams, pork shoulder picnics, boneless pork loins, and loin ends. If any of these methods are followed for the appropriate products, then FSIS would consider the products safe from *Trichinella*.

There is a great variety of processes used to prepare cured pork products (sausages, hams, pork shoulders, and other RTE products). All processes currently approved for commercial use have been tested to determine their efficiency in killing *Trichinella*. In the curing process, product is coated or injected with a salt mixture and allowed to equalize at refrigerated temperatures. Following equalization, product is dried, or smoked and dried, at various temperature/time combinations. The curing process involves the interaction of salt, temperature, and drying times to reach a desired water activity, percent moisture, or brine concentration. Unfortunately, no single or even combination of parameters achieved by curing has been shown to correlate definitively with *Trichinella* inactivation (Gamble et al, 2012). All cured products should be processed by validated methods, such as those described in this section, **"CURING."**

1. *Sausage*

The sausage may be stuffed in animal casings, hydrocellulose casings, or cloth bags. During any stage of treating the sausage to destroy live *Trichinella*, except as provided in Sausage Treatment Method 5, these coverings should not be coated with paraffin or like substance, nor should any sausage be washed during any prescribed period of drying. In the preparation of sausage, one of the following methods may be used:

Sausage Treatment Method No. 1 - Drying

The meat should be ground or chopped into pieces not exceeding three-fourths of an inch in diameter. A dry curing mixture containing not less than 3 1/3 pounds of salt to each hundredweight of the unstuffed sausage should be thoroughly mixed with the ground or chopped meat. After being stuffed, sausage having a diameter not exceeding 3 1/2 inches, measured at the time of stuffing, should be held in a drying room not less than 20 days at a temperature not lower than 45°F, except in the case of the variety of sausage known as pepperoni. If in casings not exceeding 1 3/8 inches in diameter measured at the time of stuffing, the period of drying may be reduced to 15 days. In no case, however, should the sausage be released from the drying room in less than 25 days from the time the curing materials are added, except that sausage of the variety known as "pepperoni," if in casings not exceeding the size specified, may be released at the expiration of 20 days from the time the curing materials are added. Sausage in casings exceeding 3 1/2 inches, but not exceeding 4 inches, in diameter at the time of stuffing should be held in a drying room not less than 35 days at a temperature not lower than 45 °F, and in no case, should the sausage be released from the drying room in less than 40 days from the time the curing materials are added to the meat.

Sausage Treatment Method No. 2 – Smoked, then Dried

The meat should be ground or chopped into pieces not exceeding three fourths of an inch in diameter. A dry curing mixture containing not less than 3 1/3 pounds of salt to each hundredweight of the unstuffed sausage should be thoroughly mixed with the

ground or chopped meat. After being stuffed, sausage having a diameter not exceeding 3 1/2 inches, measured at the time of stuffing, should be smoked not less than 40 hours at a temperature not lower than 80°F, and finally held in a drying room not less than 10 days at a temperature not lower than 45°F. In no case, however, should the sausage be released from the drying room in less than 18 days from the time the curing materials are added to the meat. Sausage exceeding 3 1/2 inches, but not exceeding 4 inches, in diameter at the time of stuffing, should be held in a drying room, following smoking as indicated above, not less than 25 days at a temperature not lower than 45°F, but in no case, should the sausage be released from the drying room in less than 33 days from the time the curing materials are added to the meat.

Sausage Treatment Method No. 3 – Held in Pickle Curing Medium, then Dried

The meat should be ground or chopped into pieces not exceeding three-fourths of an inch in diameter. A dry-curing mixture containing not less than 3 1/3 pounds of salt to each hundredweight of the unstuffed sausage should be thoroughly mixed with the ground or chopped meat. After adding the salt and other curing materials and before stuffing, the ground or chopped meat should be held at a temperature not lower than 34 °F for not less than 36 hours. After being stuffed, the sausage should be held at a temperature not lower than 34°F for an additional period of time sufficient to make a total of not less than 144 hours from the time the curing materials are added to the meat, or the sausage should be held for the time specified in a pickle curing medium of not less than 50° strength (salometer reading) at a temperature not lower than 44°F. Finally, sausage having a diameter not exceeding 3 1/2 inches, measured at the time of stuffing, should be smoked for not less than 12 hours. The temperature of the smokehouse during this period at no time should be lower than 90°F; and for 4 consecutive hours of this period the smokehouse should be maintained at a temperature not lower than 128°F. Sausage exceeding 3 1/2 inches, but not exceeding 4 inches, in diameter at the time of stuffing should be smoked, following the prescribed curing, for not less than 15 hours. The temperature of the smokehouse during the 15-hour period should at no time be lower than 90°F, and for 7 consecutive hours of this period the smokehouse should be maintained at a temperature not lower than 128°F. In regulating the temperature of the smokehouse for the treatment of sausage under this method, the temperature of 128°F should be attained gradually during a period of not less than 4 hours.

Sausage Treatment Method No. 4 – Dried (After Stuffing - May be Heated or Smoked, or Both Heated and Smoked)

The meat should be ground or chopped into pieces not exceeding one-fourth of an inch in diameter. A dry curing mixture containing not less than 2 1/2 pounds of salt to each hundredweight of the unstuffed sausage should be thoroughly mixed with the ground or chopped meat. After adding the salt and other curing materials and before stuffing, the ground or chopped sausage should be held as a compact mass, not more than 6 inches in depth, at a temperature no lower than 36°F for not less than 10 days. At the termination of the holding period, the sausage should be stuffed in casings or cloth bags not exceeding 3 1/3 inches in diameter, measured at the time of stuffing. After being stuffed, the sausage should be held in a drying room at a temperature not lower than 45 °F for the remainder of a 35-day period, measured from the time the curing materials are added to the meat. At any time after stuffing, if the establishment's operator deems it

desirable, the product may be heated in a water bath for a period not to exceed 3 hours at a temperature no lower than 85°F, or subjected to smoking at a temperature no lower than 80°F, or the product may be both heated and smoked as specified. The time consumed in heating and smoking, however, should be in addition to the 35-day holding period specified.

Sausage Treatment Method No. 5 – May be Coated with Paraffin while Held

The meat should be ground or chopped into pieces not exceeding three-fourths of an inch in diameter. A dry curing mixture containing not less than 3 1/3 pounds of salt to each hundredweight of the unstuffed sausage should be thoroughly mixed with the ground or chopped meat. After being stuffed, the sausage should be held for not less than 65 days at a temperature not lower than 45°F. The coverings for sausage prepared according to this method may be coated at any stage of the preparation before or during the holding period with paraffin or other substance approved by the Administrator.

Sausage Treatment Method No. 6 – Held for Two Time Periods (Holding Period and a Drying Period)

(A) Basic Requirements.

The meat should be ground or chopped into pieces not exceeding three-fourths of an inch in diameter. A dry-curing mixture containing not less than 3.33 pounds of salt to each hundred-weight of the unstuffed sausage, excluding the weight of dry ingredients, should be thoroughly mixed with the ground or chopped meat. After the curing mixture has been added, the sausage should be held for two-time periods, a holding period and a drying period. The holding period will be for a minimum of 48 hours at a room temperature not lower than 35°F. This holding period requirement may be fulfilled totally or in part before the drying period and then the remainder, if any, after the drying period or as an extension of the drying period. During the drying period, the sausage should be held in a drying room at a temperature not lower than 50°F (10.0°C) for a period determined by Tables 3, 3A, and 3B. The length of the drying period, established in Sausage Treatment Method No.6 (A) may be modified as provided in Sausage Treatment Method No.6 (B) or (C).

Table 3 - Sausage Drying Room Times by Sausage Treatment Method No. 6

Diameter of casing at time of stuffing[1]	**Days in drying room[2]**
Up to:	
1 inches	14
1 1/2 inches	15
2 inches	16
2 1/2 inches	18
3 inches	20
3 1/2 inches	23
4 inches	25

4 1/2 inches	30
5 inches	35
5 1/2 inches	43
6 inches	50

[1] The drying room times for flattened or oval sausages should use a diameter derived by measuring the circumference and dividing by 3.14 (pi).
[2] Drying room time may be modified as set forth in Tables 3B and 4.

(B) Reduction in Drying Room Time.

During the holding period, the sausage may be smoked or fermented. If the temperature is increased to 70°F (21.1°C) or higher, while the sausage is being held after adding curing materials but before the drying period, the subsequent drying room times prescribed for this method may be reduced according to the schedule in Table 3B. No interpolation of values is permissible.

Table 3A - Percentage Reduction in Drying Room Time (Table 3) Permitted by Holding Times and Temperatures Prior to Drying[1]

Minimum Temperature[2]	**Minimum Time (hours)**				
	24	**48**	**72**	**96**	**120**
70°F (21.1°C)	4	9	14	19	24
75°F (23.9°C)	5	12	19	26	33
80°F (26.7°C)	8	18	28	38	48
85°F (29.5°C)	10	25	39	53	67
90°F (32.2°C)	15	35	55	75	95
95°F (35.0°C)	23	49	74	98	100[3]
100°F (37.9°C)	37	88	100[3]	100	100
105°F (40.6°C)	57	100[3]	100	100	100
110°F (43.3°C)	90	100[3]	100	100	100
120°F (48.9°C)	100[3]	100	100	100	100

[1] In computing the days to be deducted, the number with any fraction should be rounded to the next lower whole number and should be deducted from the required total drying time. Example: Sausage stuffed in 3-inch diameter casing requires 20 days in the drying room (from Drying Room Times, Table 3). If allowed to ferment, after addition of curing materials, at 80°F for 48 hours, the 20 day drying time may be reduced 18% (from Table 3A). Eighteen percent of 20 days equals 3.6 days. Twenty days minus 3 days equals 17 days. The total drying time required in the drying room, therefore, will be 17 days.
[2] Either room temperature or internal product temperature should be used for sausages that will be subsequently dried to a moisture-protein ratio of 2.3: 1 or less. Internal product temperature should be used for all other sausages.
[3] *Trichinella* will be destroyed during fermentation or smoking at the temperature and length of time indicated. Therefore, no drying room period is required for products so treated.

(C) Reduced Salt Content-Drying Room Times.

Salt content of less than 3.33 pounds for each hundredweight of sausage formulation, excluding dry ingredients, (such as salts, sugars, and spices), may be permitted provided the drying time is increased according to the schedule contained in Table 3B.

Table 3B - Reduced Salt Content-Drying Room Times

[Required percentage increase in drying room time (Table 3) for added salt of less than 3.33 pounds per hundredweight of sausage]

Minimum pounds of salt added to sausage[1]	Percent increase in drying room time[2]
3.3	1
3.2	4
3.1	7
3.0	10
2.9	13
2.8	16
2.7	19
2.6	22
2.5	25
2.4	28
2.3	31
2.2	34
2.1	37
2.0	40

[1]Calculate the salt content for column 1 as follows: Multiply the pounds of salt in the sausage formulation by 100. Then divide this number by the total weight of sausage formulation minus the weight of dry ingredients and round down to the next lowest 0.1%. The percent salt may be substituted for pounds of salt.

Example: 120 lbs. pork, 3.56 lbs. salt, 2 lbs. spices, 0.5 lbs. wine, 1 lb. water and starter culture, 0.8 lbs. sugar, .012 lbs. sodium nitrite total weight is 127.872 lbs.

(3.56 x 100)/(127.872 - 3.56 – 2 -.8 -.012) = 356/121.5 = 2.93 pounds of salt added to sausage

Therefore, the sausage drying time must be increased by 13 percent.

[2] In computing the days to be added to the required total drying time, fractions should be rounded to the next higher whole number and added to the required total drying time. Example: Sausage stuffed in 3 1/2 inch diameter casing requires 23 days in the drying room (from Drying Room Times, Table 3). If the quantity of salt added per hundredweight of sausage is 2 pounds instead of 3.33 pounds, the drying room time must be increased by 40 percent (from Reduced Salt Content-Drying Room Times, Table 3B), or 9.2 days. The 9.2 is rounded up to 10 days and is added to the 23 days to equal 33 days. The total drying time required in the drying room for the scenario presented, therefore, will be 33 days.

Sausage Treatment Method No. 7 – Holding, Heating, and Drying Treatment

Dry Sausages.

(A) General Requirements. The establishment should use meat particles reduced in size to no more than 1/4 inch in diameter. The establishment should add a curing mixture containing no less than 2.7 pounds of salt per hundred pounds of meat and mix it

uniformly throughout the product. The establishment should hold, heat, and dry the product according to paragraph (B) or (C) below.

(B) Holding, Heating, and Drying Treatment, Large Sausages. Except as permitted in (C) below, the establishment should subject sausages in casings not exceeding 105 mm in diameter, at the time of stuffing, to all of the following minimum chamber temperatures and time periods.

Table 3C - Treatment Schedule for Sausages 105 Millimeters (4 1/8 inches) or Less in Diameter

Minimum chamber temperature		**Minimum time (hours)**
(°F)	(°C)	
50	10	12
90	32.2	1
100	37.8	1
110	43.3	1
120	48.9	1
125	51.7	7

Following the preceding treatment, the establishment should dry the sausages at a temperature not lower than 50°F (10°C) for not less than 7 days.

(C) Heating and Drying Treatment, Small Sausages. Alternatively, the establishment may subject sausages in casings not exceeding 55 mm in diameter, at the time of stuffing, to all of the following minimum chamber temperatures and time periods.

Table 3D - Treatment Schedule for Sausages 55 Millimeters (2 1/8 inches) or Less in Diameter

Minimum chamber temperature		**Minimum time (hours)**
(°F)	**(°C)**	
50	10	12
100	37.8	1
125	51.7	6

Following the preceding heat treatment, the establishment should dry the sausages at a temperature not lower than 50°F (10°C) for not less than 4 days.

2. Capicollo (Capicola, Capacola)

Boneless pork butts for *capocollo* should be cured in a dry curing mixture containing no less than 4 1/2 pounds of salt per hundredweight of meat for a period of no less than 25

days at a temperature no lower than 36°F. If the curing materials are applied to the butts by the process known as churning, a small quantity of pickle may be added. During the curing period the butts may be overhauled (turned over for the application of additional cure) according to any of the usual processes of overhauling, including the addition of pickle or dry salt if desired. The butts should not be subjected during or after curing to any treatment designed to remove salt from the meat, except that superficial washing may be allowed. After being stuffed, the product should be smoked for a period of not less than 30 hours at a temperature not lower than 80°F, and should finally be held in a drying room for not less than 20 days at a temperature not lower than 45°F.

3. *Coppa*

Boneless pork butts for coppa should be cured in a dry curing mixture containing no less than 4 1/2 pounds of salt per hundredweight of meat for a period of no less than 18 days at a temperature no lower than 36°F. If the curing mixture is applied to the butts by the process known as churning, a small quantity of pickle may be added. During the curing period the butts may be overhauled according to any of the usual processes of overhauling, including the addition of pickle or dry salt if desired. The butts should not be subjected during or after curing to any treatment designed to remove salt from the meat, except that superficial washing may be allowed. After being stuffed, the product should be held in a drying room for not less than 35 days at a temperature not lower than 45°F.

4. Hams and Pork Shoulder Picnics

In the curing of hams and pork shoulder picnics, one of the methods below should be used. For calculating days per pound, the establishment should use the weight of the heaviest ham or picnic in the lot.

Ham and Pork Shoulder Picnics Method No. 1 – Dry Salt Curing Process

The hams and pork shoulder picnics should be cured by a dry salt curing process for not less than 40 days at a temperature no lower than 36°F. The products should be laid down in salt, not less than 4 pounds to each hundredweight of product, the salt being applied in a thorough manner to the lean meat of each item. When placed in cure, the products may be pumped with pickle if desired. At least once during the curing process, the products should be overhauled and additional salt applied, if necessary, so that the lean meat of each item is thoroughly covered. After removal from cure, the products may be soaked in water at a temperature no higher than 70°F for not more than 15 hours, during which time the water may be changed once, but the products should not be subjected to any other treatment designed to remove salt from the meat except that superficial washing may be allowed. The products should finally be dried or smoked at a time and temperature not less than a combination prescribed in Table 3F, titled Ham and Pork Shoulder Picnics Method No. 2.

Ham and Pork Shoulder Picnics Method No. 2 – Controlled Temperature Methods for, Curing (other than Bag Curing) and Bag Curing followed by Drying

(A) Curing (other than Bag Curing)

Establishments should cure hams and shoulders by using a cure mixture containing not less than 70 percent salt by weight to cover all exposed muscle tissue and to pack the hock region. Total curing time consists of a mandatory cure contact time and an optional equalization time.

(B) Cure Contact Time

Establishments should keep exposed muscle tissue coated with the cure mixture at least 28 days but for no less than 1.5 days per pound of ham or shoulder. This is referred to as the cure contact time. Overhaul is optional during the cure contact time if the exposed muscle tissue remains coated with the curing mixture.

(C) Equalization

The establishment may provide an equalization period after the minimum cure contact time in (B) above to permit the absorbed salt to permeate the product's inner tissues. Equalization is the period after the excess cure has been removed from the product at the end of the cure contact period up until the product is placed in the drying room and the drying period begins. The total curing time (cure contact plus equalization should be at least 40 days and in no case less than 2 days per pound of an uncured ham or shoulder.

(D) Removing Excess Cure

After the required cure contact period, the establishment may remove excess cure mixture from the product's surface mechanically or by rinsing up to 1 minute with water, but not by soaking.

(E) Bag Curing.

Bag curing is a traditional ham curing technique in which the manufacturer wraps the ham and all the cure mixture together in Kraft paper then hangs each ham individually. The paper keeps the extra cure mixture in close contact with the product making reapplication of salt unnecessary, and it protects the product from mites and insects. Establishments may employ the bag curing method as an alternative to (A) through (D) above. An establishment which elects to use the bag curing method should apply a cure mixture containing at least 6 pounds of salt per 100 pounds of uncured product. The establishment should rub the curing mixture into the exposed muscle tissue, pack the hock region with the curing mixture, and use uncoated wrapping paper to wrap the product together with any remaining curing mixture. The bag-cured product should remain wrapped throughout the curing period and may or may not remain wrapped during the drying period. In any case, the curing period should be at least 40 days but not less than 2 days per pound of an uncured ham or shoulder. After curing, the cured product should be exposed to a drying time and temperature prescribed in Table 3F.

(F) Curing Temperature

During the curing period the establishment should use one of the following procedures: (1) The establishment should control the room temperature at not less than 35°F (1.7°C) nor greater than 45°F (7.2°C) for the first 1.5 days per pound of an uncured ham or shoulder, and not less than 35°F (1.7°C) nor greater than 60°F (15.6°C) for the remainder of the curing period. (2) The establishment should monitor

and record daily product temperature. The room temperature need not be controlled but days on which the product temperature drops below 35°F (1.7°C) should not be counted as curing time. If the product temperature exceeds 45°F (7.2°C) within the first period of 1.5 days (per pound of an uncured ham or shoulder) or if the product temperature exceeds 60°F (15.6°C), during the remainder of the curing period the establishment should cool the product back to the appropriate temperature for the curing period as described above. (3) The establishment should begin curing product only between the dates of December 1 and February 13. The room temperature need not be controlled, but the establishment should monitor and record daily room temperatures, and days in which the room temperature drops below 35°F (1.7°C) should not be counted as curing time.

(G) Drying

After the curing period, establishments should use one of the following three procedures for drying. (1) The establishment should subject the product to a controlled room temperature for a minimum time and minimum temperature combination prescribed in Table 3F or for a set of such combinations in which the total of the fractional periods (in column 4 of Table 3F) exceeds 1.5. (2) Establishments using uncontrolled room temperatures should monitor and record the internal product temperature. The drying period should be complete when, from the days which can be counted as curing time, one of the time/temperature combinations of Table 3F is satisfied or when the total of the fractional values for the combinations exceeds 1.5. (3) Establishments using uncontrolled room temperatures should dry the product for a minimum of 160 days including the entire months of June, July, and August. This procedure is obviously dependent on local climatic conditions and no problem exists with respect to current producers who use this procedure. Future applicants should demonstrate that their local monthly average temperatures and the local monthly minimum temperatures are equal to or warmer than the normal average temperatures and normal minimum temperatures compiled by the National Oceanic and Atmospheric Administration for Boone, North Carolina, station 31-0977, 1981 through 2010.

Table 3E - Monthly Temperature (° F) for Boone NC, 1981-2010[1]

Jan.	Feb.	Mar.	Apr.	May	June	July	Aug.	Sep.
Normal average temperatures								
31.5	34.0	40.5	49.0	57.5	65.0	68.5	67.5	61.0
Normal minimum temperatures								
21.0	23.0	29.0	37.0	46.0	54.0	58.0	57.0	50.0

[1] https://www.currentresults.com/Weather/North-Carolina/Places/boone-temperatures-by-month-average.php

Drying Times and Temperatures for *Trichinella* Inactivation in Hams and Shoulders

Table 3F - Minimum Drying Days at a Minimum Temperature*

Minimum drying temperature		Minimum days at drying temperature	Fractional period for one day of drying
Degrees F	**Degrees C**		
130	54.4	1.5	.67
125	51.7	2	.50
120	48.9	3	.33
115	46.1	4	.25
110	43.3	5	.20
105	40.6	6	.17
100	37.8	7	.14
95	35.0	9	.11
90	32.2	11	.091
85	29.4	18	.056
80	26.7	25	.040
75	23.9	35	.029

* Interpolation of these times or temperatures is not acceptable; establishments wishing to use temperatures or times not in this Table should first validate their efficacy.

Ham and Pork Shoulder Picnics Method No. 3 - Controlled Temperature Methods for Drying Curing

(A) Cure

Establishments should cure hams and shoulders by using a cure mixture containing not less than 71.5 percent salt by weight to cover all exposed muscle tissue and to pack the hock region. Establishments may substitute potassium chloride (KCl) for up to half of the required salt on an equal weight basis.

(B) Curing

Establishments should apply the cure at a rate of not less than 5.72 pounds of salt and KCl per hundred pounds of fresh meat. The cure should be applied in either three or four approximately equal amounts (two or three overhauls) at separate times during the first 14 days of curing.

(C) Cure Contact Time

Establishments should keep the product in contact with the cure mixture for no less than 2 days per pound of an uncured ham or shoulder but for at least 30 days. Establishments should maintain the curing temperature at no less than 35°F (1.7°C) during the cure contact time.

(D) Equalization

After the cure contact period, establishments should provide an added equalization period of no less than 1 day per pound of an uncured ham or shoulder but at least 14 days. Equalization is the time after the excess cure has been removed from the product, the end of the cure contact period, and before the drying period begins. Establishments may substitute additional cure contact days for an equal number of equalization days.

(E) Removing Excess Cure

After the required cure contact period, the establishment may remove excess cure mixture from the product's surface mechanically or by rinsing up to 1 minute with water, but not by soaking.

(F) Drying

After the curing period, establishments should use one of the controlled temperature methods for drying listed in Ham and Pork Shoulder Picnics Method No. 2 of this subparagraph.

Ham and Pork Shoulder Picnics Method No. 4 – Dry Curing at a Minimum Temperature of 55°F (13°C) for at Least 150 Days

(A) Curing

The establishment should cure the ham to a minimum brine concentration of 6 percent by the end of the drying period. Brine concentration is calculated as 100 times the salt concentration divided by the sum of the salt and water concentrations.
Percent brine = 100 x [salt] / ([salt] + [water])
The Agency will accept the brine concentration in the biceps femoris as a reasonable estimate of the minimum brine concentration in the ham.

(B) Drying and Total Process Times

The establishment should dry the cured ham at a minimum temperature of 55°F (13°C) for at least 150 days. The total time of drying plus curing should be at least 206 days.

(C) Ensuring an Acceptable Internal Brine Concentration

(1) To establish process compliance, the establishment should take product samples from the first 12 lots of production as follows: From each lot, (i) One sample should be taken from each of 5 or more hams; (ii) Each sample should be taken from the biceps femoris. As an alternative to the use of the biceps femoris, the Agency will consider other methods of sampling dry cured hams to determine the minimum internal brine concentration, as long as the establishment submits data and other information to establish the alternative method's sufficiency to the processing authority; (iii) Each sample should weigh no less than 100 grams; (iv) The samples should be combined as one composite sample and sealed in a water vapor proof container; (v) The composite sample should be submitted to an accredited laboratory to be analyzed for salt and water content using validated methods. If the time between sampling and submittal of the composite sample to the accredited laboratory will exceed 8 hours, then the establishment should

freeze the composite sample immediately after the samples are combined; (vi) Once the laboratory results for the composite sample are received, the manufacturer should calculate the internal brine concentration by multiplying the salt concentration by 100 and then dividing that figure by the sum of the salt and water concentrations; (vii) Compliance is established when the samples from the first 12 lots of production have a minimum internal brine concentration of 6 percent. Lots being tested to establish compliance should be held until the internal brine concentration has been determined and found to be at least 6 percent. If the minimum internal brine concentration is less than 6 percent, the lot being tested should be held until the establishment brings the lot into compliance by further processing. (2) To maintain compliance through on-going verification, the establishment should take samples, have the samples analyzed, and perform the brine calculations as set forth above at a minimum for one lot every 13 weeks. Lots being tested to maintain compliance as part of on-going verification do not need to be held. If the minimum internal brine concentration is less than 6 percent in a lot being tested as part of on-going verification, the establishment must take corrective action and develop and propose steps acceptable to FSIS to ensure that the process is corrected. (3) Accredited laboratory results and the brine calculations should be placed on file at the establishment and available for review by FSIS inspection as HACCP verification records.

<u>Ham and Pork Shoulder Picnics Method No. 5 - Dry Curing at a Minimum Temperature of 110°F (43°C) for at Least 4 Days</u>

(A) Curing

The establishment should cure the ham to a minimum brine concentration of 6 percent by the end of the drying period. Brine concentration is calculated as 100 times the salt concentration divided by the sum of the salt and water concentrations. Percent brine = 100 x [salt] / ([salt] + [water])

The Agency will accept the brine concentration in the biceps femoris as a reasonable estimate of the minimum brine concentration.

(B) Drying and Total Process Times

The establishment should dry the cured ham at a minimum temperature of 110°F (43°C) for at least 4 days. The total time of drying plus curing should be at least 34 days.

(C) Ensuring an Acceptable Internal Brine Concentration

(1) To establish process compliance, the establishment should take product samples from the first 12 lots of production as follows: From each lot, (i) One sample should be taken from each of 5 or more hams; (ii) Each sample should be taken from the biceps femoris. As an alternative to the use of the biceps femoris, the Agency will consider other methods of sampling the dry cured hams to determine internal brine concentration, if the establishment validates the alternative sampling method. (iii) Each sample should weigh no less than 100 grams; (iv) The samples should be combined as one composite sample and sealed in a water vapor proof container; (v) The composite sample should be submitted to an accredited laboratory to be analyzed for salt and water content using validated methods. If the time between

sampling and submittal of the composite sample to the accredited laboratory will exceed 8 hours, then the establishment should freeze the composite sample immediately after the samples are combined; (vi) Compliance is established when the samples from the first 12 lots of production have a minimum internal brine concentration of 6 percent. Lots being tested to establish compliance should be held until the internal brine concentration has been determined and found to be at least 6 percent. If the minimum internal brine concentration is less than 6 percent, the lot being tested should be held until the establishment brings the lot into compliance by further processing. (2) To maintain compliance through on-going verification, the establishment should take samples, have the samples analyzed, and perform the brine calculations as set forth above at a minimum from one lot every 13 weeks. Lots being tested to maintain compliance as part of on-going verification do not need to be held. If the minimum internal brine concentration is less than 6 percent in a lot tested to maintain compliance, the establishment must take corrective action and develop and propose steps acceptable to FSIS to ensure that the process is corrected. (3) Accredited laboratory results and the brine calculations should be placed on file in the establishment and available to FSIS inspection for review.

5. *Boneless Pork Loins and Loin Ends*

In place of heating or freezing to destroy live *Trichinella* in boneless loins, the loins may be cured for a period of not less than 25 days at a temperature not lower than 36°F using one of the following methods:

Boneless Loins Method No. 1 - Application of Dry Salt Curing Mixture

Application of a dry salt curing mixture containing no less than 5 pounds of salt to each hundredweight of meats.

Boneless Loins Method No. 2 - Application of Pickle Solution

Application of a pickle solution of not less than 80° strength (salometer); pickle solution should be applied to achieve not less than 60 pounds of pickle to each hundredweight of meat.

Boneless Loins Method No. 3 - Application of Pickle Solution added to the Dry Salt Cure

Application of a pickle solution added to the dry salt cure prescribed as Boneless Loins Method No. 1 in this section provided the pickle solution is not less than 80° strength (salometer). After removal from the cure, the loins may be soaked in water for not more than 1 hour at a temperature not higher than 70°F or washed under a spray but should not be subjected, during or after the curing process, to any other treatment designed to remove salt. Following curing, the loins should be smoked for not less than 12 hours. The minimum temperature of the smokehouse during this period at no time should be lower than 100°F, and for 4 consecutive hours of this period the smokehouse should be maintained at a temperature not lower than 125°F. Finally, the product should be held in a drying room for a period of no less than 12 days at a temperature no lower than 45°F.

6. "*Country Ham," "Country Style Ham," "Dry Cured Ham," "Country Pork Shoulder," "Country Style Pork Shoulder," and "Dry Cured Pork Shoulder"*

Country Ham, Country Style Ham, or Dry Cured Ham, and Country Pork Shoulder, Country Style Pork Shoulder, or Dry Cured Pork Shoulder are the uncooked, cured, dried, smoked or unsmoked meat food products made respectively from a single piece of meat conforming to the definition of "ham", or from a single piece of meat from a pork shoulder. These products must be treated for the destruction of live *Trichinella* using tested and approved methods. These products are prepared by the dry application of salt (NaCl), or by the dry application of salt (NaCl) and one or more of the optional ingredients listed below. These products may not be injected with curing solutions or placed in curing solutions. Listed below are 4 dry application options.

(1) The entire exterior of the ham or pork shoulder should be coated by the dry application of salt or by the dry application of salt combined with other ingredients as permitted in paragraph (d) of this section.

(2) Additional salt, or salt mixed with other permitted ingredients, may be re-applied to the product as necessary to insure complete penetration.

(3) When sodium or potassium nitrate, or sodium or potassium nitrite, or a combination thereof, is used, the application of salt should be in sufficient quantity to ensure that the finished product has an internal salt content of at least 4 percent.

(4) When no sodium nitrate, potassium nitrate, sodium nitrite, potassium nitrite or a combination thereof is used, the application of salt should be in sufficient quantity to ensure that the finished product has a brine concentration of not less than 10 percent or a water activity of not more than 0.92.

The optional ingredients for these products are: (1) Nutritive sweeteners, spices, seasonings and flavorings; and (2) Sodium or potassium nitrate and sodium or potassium nitrite.

General Instructions for Recording Thermometers

When necessary to comply with heating, freezing, and curing treatment requirements described in this section, the smokehouses, drying rooms, and other compartments used in the treatment of pork to destroy live *Trichinella* must be suitably equipped, by the operator of the official establishment, with accurate automatic recording thermometers. Equipment such as automatic recording thermometers or any thermometers used in drying rooms, and other compartments must be checked periodically to make sure they are functioning accurately.

Special Consideration for Certain Processes that do not rely on High Temperatures to Control Trichinella in Pork

Certain processes, including those used to produce dried, salt-cured, or fermented products, do not rely on high temperatures to control *Trichinella*. Establishments need to ensure that further controls are in place to control *Trichinella* when such processes are used to produce these types of pork products. An establishment that processes a dried,

salt-cured, or fermented/acidified product must address *Trichinella* in their HACCP system, and must also have written documentation to support the decisions made in their hazard analysis. An establishment must validate its process (i.e., either CCPs or prerequisite programs) used to eliminate *Trichinella* when it is determined to be RLTO in the production process.

As previously discussed in "**CURING**," the effectiveness of curing to eliminate *Trichinella* larvae is dependent upon a combination of various processing parameters and on the product formulation; specifically, on the temperature and time of fermentation/drying and the salt level, respectively. Unfortunately, no single or even combination of parameters achieved by curing has been shown to correlate definitively with *Trichinella* inactivation (Gamble et al, 2012). All cured products should be processed by validated methods, such as those described in this section, **"CURING."**

HIGH PRESSURE PROCESSING (HPP)

HPP is an antimicrobial treatment for use on meat, poultry, and processed egg products. HPP exposes food to elevated pressures, with or without the addition of heat, to inactivate microorganisms and extend microbiological shelf life. HPP treatment has been shown to be effective in eliminating *Trichinella spiralis*. In one study (Porto-Fett et al., 2010), HPP treatment of either 483 or 600 megapascals (MPa) for 1.0 or 0.5 min, respectively, was effective in inactivating *Trichinella spiralis* larvae in masseter muscle (about 3.4 log larvae/g) collected from infected swine.

Therefore, it is recommended that a HPP treatment of a minimum of 483 MPa for 1 minute be used to eliminate *Trichinella* in pork.

(**Note** – 300 MPa = 29,007 psi (pounds per square inch); 483 MPa = 70,053 psi; and 600 MPa = 87,022 psi.)

IRRADIATION

Treatment of fresh pork with 40 - 50 krad (0.4 – 0.6 kGy) of cesium-137 has been proven to render *Trichinella* completely non-infective. Irradiation with cobalt-60 or high energy x-rays at this same level should also be effective for inactivating these parasites.

Option 5: Develop alternative *Trichinella* control procedures not included in Option 4

Establishments may decide to develop alternative procedures to control *Trichinella*. If so, establishments must ensure that their alternative procedures are properly validated. FSIS developed FSIS Compliance Guideline HACCP Systems Validation to provide establishments with assistance in meeting the validation requirements in 9 CFR 417.4 and to ensure that their HACCP systems are properly validated.

Control of Other Parasitic Hazards in Pork Products

Producers of RTE or NRTE pork products must also assess in their hazard analysis whether other parasites in addition to *Trichinella* are hazards that are RLTO in their production processes (9 CFR 417.2). If establishments determine that other parasites represent a hazard that is RLTO, then they must include control procedures for these parasites in their HACCP plans. Options 4-5 may be used to control other parasites in addition to *Trichinella* in pork products. Further, establishments are required to have documentation that supports the decisions made in their hazard analysis as a part of their records in accordance with 9 CFR 417.5(a)(1). As with *Trichinella*, establishments must list the CCPs designed to control other parasites [9 CFR 417.2(c)(2)] and the critical limits that must be met at each of the CCPs [9 CFR 417.2(c)(3)]. Establishments may determine in their hazard analysis that other parasites are NRLTO in their pork products if they are prevented by using a prerequisite program. If this is the case, Options 1-3 may be used to prevent other parasites in the establishment's pork products.

In addition to *Trichinella*, *Toxoplasma gondii* (*Toxoplasma*) is a protozoan parasite of public health significance. *Toxoplasma* can cause toxoplasmosis, and infects most species of warm-blooded animals, including humans. Members of the family Felidae (domestic cats and their relatives) are the primary host for *Toxoplasma*. Felids can contaminate the

KEY DEFINITIONS

Toxoplasmosis is caused by the protozoan parasite *Toxoplasma gondii* (*Toxoplasma*). *Toxoplasma* infects most species of warm blooded animals, including humans, and can cause the disease toxoplasmosis.

The only known definitive hosts for *Toxoplasma* are members of family Felidae (domestic cats and their relatives). Members of the cat family are infected by eating animals infected with cysts of *Toxoplasma* parasites. Cats can also become infected by ingesting *Toxoplasma* eggs (oocysts) from contaminated food or water. *Toxoplasma* completes its life cycle in the cat, which produces millions of *Toxoplasma* eggs in its stool. Once outside of the cat, the eggs mature and become infectious for people and other animals. The tissue form of *Toxoplasma* (a microscopic cyst consisting of bradyzoites, a slower reproducing form contained in tissue cysts) can be transmitted to humans by food. People become infected by:

- Eating undercooked, contaminated meat (especially pork, lamb, and venison)
- Accidental ingestion of undercooked, contaminated meat after handling it and not washing hands thoroughly (*Toxoplasma* cannot be absorbed through intact skin; however, *Toxoplasma* cysts containing bradyzoites can be inadvertently ingested from small bits of meat on the hands, and *Toxoplasma* tachyzoites have been shown to penetrate intact mucous membranes).
- Eating food that was contaminated by knives, utensils, cutting boards, or other foods that had contact with raw, contaminated meat.

environment by excreting the environmentally resistant stage of this parasite, the oocyst, in their feces (Jones et al., 2012). Domestic food animals, including swine, can be infected by *Toxoplasma*, and infected animals can harbor *Toxoplasma* cysts in muscle tissue. Humans can become infected by ingesting tissue cysts from raw or undercooked meat (Hill et al., 2010).

Toxoplasmosis is one of the most common parasitic infections in humans. *Toxoplasma* is the second leading cause of death due to foodborne illnesses in the United States, accounting for an estimated 327 deaths annually. *Toxoplasma* is also the fourth leading cause of hospitalizations related to foodborne illnesses, accounting for an estimated 4,428 hospitalizations annually (Scallan et al., 2011).

The risk of infection with *Toxoplasma* is significantly increased in pasture raised swine that are exposed to cat feces in soil, grass, feed, or water (Jones et al., 2012). In the U.S., the prevalence of *Toxoplasma* in confinement raised swine is approximately 2.7% (Hill et al., 2010). For swine raised in pastures, the prevalence has been reported to be between 50-100% (Gamble et al., 2000). The risk of infection in swine that are raised outdoors is increased because of potential exposure to soil contaminated with *Toxoplasma* oocysts (Hill et al., 2012; Hill et al., 2010).

Compliance with the HACCP regulations for RTE products will ensure the reduction of *Toxoplasma*. However, there are no certification programs to address the risk of *Toxoplasma* infection in swine (http://porkgateway.org/resource/toxoplasma/). Prevention of *Toxoplasma* infection in swine is achieved through GPPs on the farm, including:

- Creating a level of biosecurity that reduces or eliminates exposure of swine to cats and wildlife (e.g., bobcats, raccoons, skunks, and opossums) that may be infected with *Toxoplasma*.
    - Eliminating feral cats and securing feed, water, and swine areas from access by cats. The contribution of cats to the spread of *Toxoplasma* infection in swine cannot be overemphasized.
- Establishing and maintaining an effective rodent control program.
- Preventing cannibalism among swine within an infected herd through the prompt removal of dead swine.
- Changing or thoroughly washing boots before entering barns to avoid tracking in oocysts.
- Preventing deliberate or inadvertent feeding of raw or undercooked meat scraps.

There is no available direct testing method that can be performed at slaughter for *Toxoplasma*. If the establishment identifies *Toxoplasma* as a hazard RLTO, then the establishment will have to use a validated process that effectively eliminates this parasitic hazard. The methods for heating, freezing, HPP, and irradiation that are used to eliminate *Trichinella* in pork products are also sufficient to eliminate *Toxoplasma* from pork products. For *Toxoplasma*, HPP treatment of equal to or greater than 300 MPa for

30 seconds is effective in eliminating *Toxoplasma* tissue cysts in ground pork (Lindsay et al., 2006).

NOTE: The available information on the effect of various curing processes on *Toxoplasma* is limited and additional studies are needed to determine the effectiveness of curing for the destruction of *T. gondii* in pork and pork products. However, pumping of pork products with salt solutions containing 2% NaCl or ≥1.4% potassium or sodium lactate has been shown to inactivate *T. gondii* tissue cysts in pork (Gamble et al, 2012).

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