The first edition of the Compliance Guideline contains recommendations for controlling *Salmonella* in Market Hogs from pre-*harvest through slaughter.*

Compliance Guideline for Controlling *Salmonella* in Market Hogs

First Edition
December 2013

This is the first edition of the Compliance Guideline for Controlling *Salmonella* in Market Hogs. Recommendations are included for controlling *Salmonella* from pre-harvest through the slaughter process.

This draft guideline represents FSIS's current thinking on the control of *Salmonella* in market hogs. Therefore, even though this is a draft document, FSIS encourages market hog slaughter establishments to incorporate information in this guidline in their decision making process. FSIS encourages further study and solutions by industry for controlling and reducing the spread of *Salmonella* in hog slaughter facilities.

FSIS is seeking comments on this guidance document as part of its efforts to continuously assess and improve the effectiveness of policy documents. FSIS requests that all interested persons submit comments regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. The comment period will be 60 days. The draft will be updated in response to comments.

Comments may be submitted by either of the following methods:

1. Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to: http://www.regulations.gov and follow the online instructions at that site for submitting comments.

2. Mail, including CD-ROMs, etc.: Send to Docket Room Manager, U.S. Department of Agriculture (USDA), FSIS, 1400 Independence Avenue SW, Patriots Plaza 3, Mailstop 3782, 8-163B, Washington, DC 20250-3700.

3. Hand- or courier-delivered items: Send to Docket Room Manager, U.S. Department of Agriculture (USDA), FSIS, 1400 Independence Avenue SW, Patriots Plaza 3, Mailstop 3782, 8-163B, Washington, DC 20250-3700.

   Instructions: All items submitted by mail or electronic mail must include the Agency name, FSIS, and document title: FSIS Compliance Guideline for Controlling *Salmonella* in Market Hogs; docket number: FSIS-2012-0026. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information to: http://www.regulations.gov.

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I. Purpose

The purpose of this guidance document is to provide information on best practices that may be used at slaughter establishments to prevent, eliminate, or reduce levels of *Salmonella* on hogs.
This guidance also references scientific studies that indicate lairage is a significant factor in the spread of *Salmonella*. FSIS encourages further study and solutions by industry in controlling and reducing the spread of *Salmonella* in hog slaughter facilities.

This guidance provides information on best practices that may be used at slaughter to prevent, eliminate, or reduce levels of *Salmonella* in market hogs.

This guidance targets hog establishments and discusses recommended best practices that would help them better comply with the relevant regulatory requirements (9 CFR 310.7, 310.10, 310.11, 310.12, 310.18, 310.25, Part 416, and Part 417).

This guidance document includes suggestions for establishments to improve their slaughter management practices to address *Salmonella*. When an establishment makes changes at the appropriate processing locations, process control should result in raw pork products that have less contamination with pathogens including *Salmonella*.

This guidance document also describes steps involved in the hog slaughter process and production of raw products. Each slaughter step section targets best practice recommendations for *Salmonella* contamination control.
The document includes information on farm rearing and transport that establishments may share with their suppliers or producers that provide market hogs to them. The guideline also includes supplemental information for controlling parasitic hazards; *Trichinella spiralis; and Toxoplasma gondii* (Attachment 1).
The reference list at the end of the document provides resource material.

Key Points:

- **This guidance references scientific studies that indicate lairage is a significant factor in the spread of *Salmonella*.**

II. Introduction

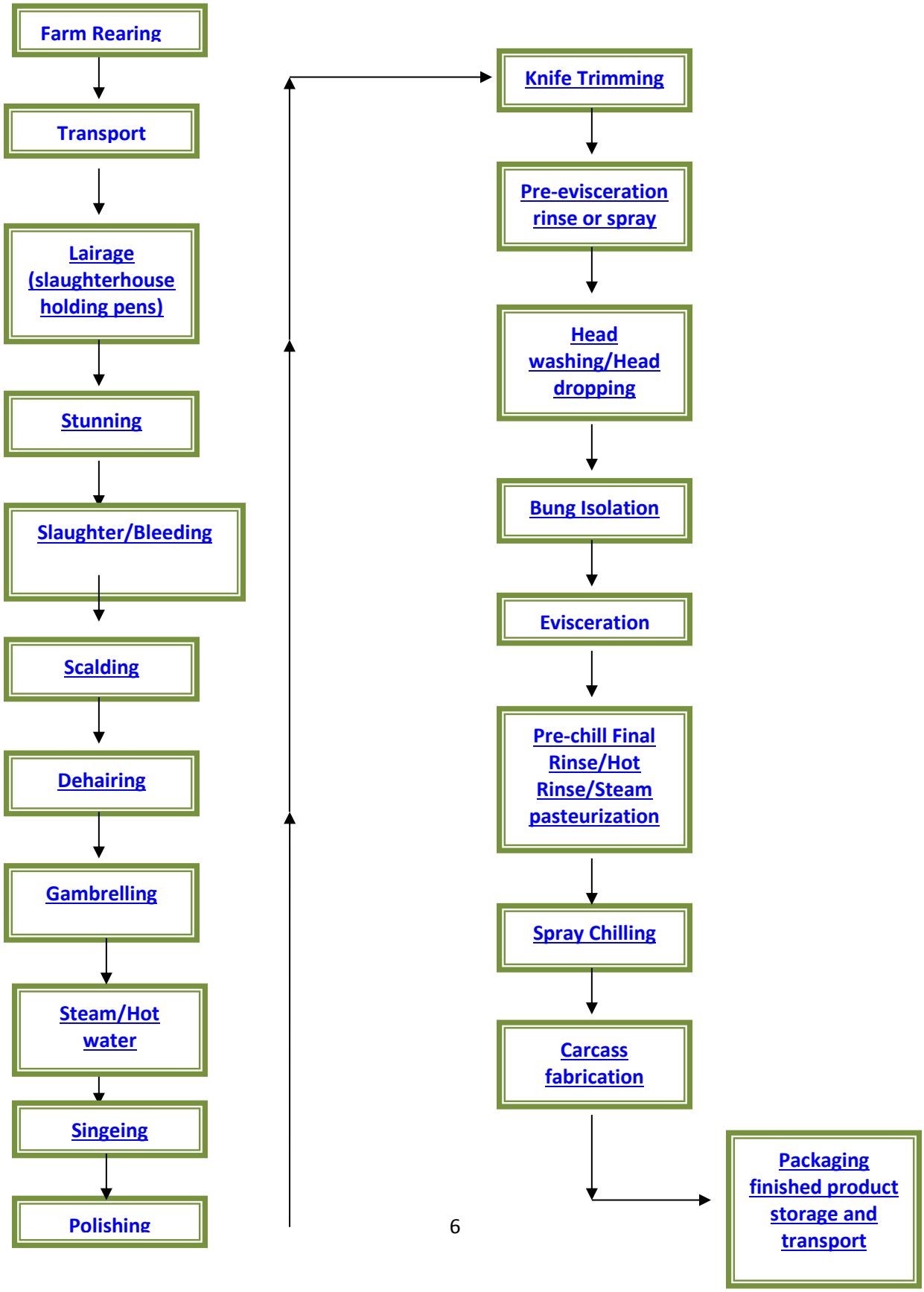
Establishments should slaughter and process market hogs in a manner designed to prevent or reduce contamination from occurring at every step of the processes (shown in fig. 1) and should use decontamination and antimicrobial intervention treatments as necessary to address any contamination that: (a) may result from the implementation of the slaughter process or (b) otherwise occurs on the carcasses.

Key Points:

- **Maintain adequate sanitation in pens**
- **Maintain adequate sanitary separation between each carcass, and between parts and viscera during dressing**
- **Routinely clean and sanitize equipment and hand tools that are used to prepare for presentation prior to opening, and remove contamination after cutting into the carcass**
- **Design and arrange equipment to prevent the contact of successive carcasses and carcass parts with contaminated equipment**
- **Frequently wash hands and aprons that come in contact with carcasses**
- **Implement decontamination and antimicrobial intervention treatments**

Figure 1.

Hog Slaughter Processing Steps



III. Public Health Relevance

Nontyphoidal *Salmonella* is the most common cause of bacterial food borne illness, accounting for 11% of food borne illnesses (about 1 million illnesses), 35% of hospitalizations and 28% of deaths. *Campylobacter* accounts for approximately 9% of food borne illnesses (about 845,000 illnesses) and 15% of hospitalizations (Scallan et al., 2011a). Swine can harbor both pathogens, though at varying levels (Zhao et al., 2001, 2010). Outbreaks resulting in human *Salmonella* illnesses involving pork have been consistently identified on an annual basis, suggesting pork as a vehicle for salmonellosis. Between 2000 and 2007, approximately four outbreaks and one hundred and two illnesses per year, on average, have been associated with pork. These estimates were calculated for outbreaks where pork was sole implicated food vehicle or identified as the sole contaminated ingredient. A yearly comparison shows from 2000 to 2007 there were five, seven, three, three, four, three, three and seven outbreaks, respectively. Among the eight years of data, 2007 had the most salmonellosis cases associated with pork consumption at 236 illnesses. For additional information please visit the Centers for Disease Control and Preventions (CDC) foodborne illness outbreak website at: http://www.cdc.gov/foodborneoutbreaks/.
Four *Campylobacter* outbreaks were associated with pork (CDC, 1998 to 2008). During the Market Hog Baseline shake down period, *Campylobacter* was not detected. Subsequently, *Campylobacter* was not sampled for during the Nationwide Market Hogs Microbiological Baseline Survey baseline testing 2010 to 2011.

Outbreaks resulting in human Salmonella illnesses involving pork have been consistently identified on an annual basis, suggesting pork as a vehicle for salmonellosis.

Under the 1996 Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) final rule, FSIS established *Salmonella* performance standards for several raw product classes, including market hogs, as a means of verifying that establishments control food safety hazards in fresh meat processing. FSIS verifies the performance standards by conducting the *Salmonella* verification testing program, in which FSIS samples and analyzes sets of chilled carcasses for *Salmonella.*

Results from *Salmonella* verification sets for CY 1998 to 2010 may be found at the following link:
http://www.fsis.usda.gov/Science/Progress_Report_Salmonella_Testing_tables/index.asp.

In 2006, FSIS announced several new policies in the Federal Register Notice (FRN), *Salmonella* Verification Sample Result Reporting: Agency Policy and Use in Public Health Protection *(71 FR 9772)* intended to strengthen the *Salmonella* Verification Program including:

- Develop a more risk-based algorithm as a means to more frequently schedule sampling in the higher risk establishments.
- Report each individual *Salmonella* result to each establishment as soon as it becomes available.
- Post quarterly nationwide *Salmonella* data showing aggregate results of sample set results by product class. *See* Quarterly *Salmonella* Results.
- Conduct Food Safety Assessments (FSAs) in establishments failing its *Salmonella* standards, or showing poor process control.
- Provide serotype data on verification set results as soon as results are available.
- Work more closely with other federal and state public health agencies to develop sub-typing policies.
- Conduct additional Nationwide Microbiological Baselines to develop tightened performance standards for *Salmonella* (and *Campylobacter* if applicable*).*

In July, 2011 FSIS implemented updated *Salmonella* performance standards and new *Campylobacter* performance standards for young chickens and turkeys.
These standards were developed from Nationwide Microbiological Baselines.
With these new lower standards in poultry; market hogs now have the highest permissible standard (8.7 percent) for *Salmonella* of all raw carcass product classes.
For an establishment to meet this standard there can be no more than six *Salmonella* positives in the 55 analyzed samples (referred to as a "set").

FSIS conducted the Nationwide Microbiological Baseline Data Collection Program; Market Hog Survey, from August 2010 to August 2011. FSIS has completed two previous nationwide surveys in market hogs. The first FSIS nationwide market hog microbiological baseline data collection was in April 1995 to March 1996 and the second FSIS nationwide pork microbiological baseline data collection was in June 1997 to May 1998.

FSIS designed and performed this most recent survey to estimate the percent positive and levels of microbiological pathogens and indicator bacteria on market hog carcasses. During the survey, FSIS collected sponge samples at pre-evisceration and post-chill from two separate shifts from the belly, ham, and jowl portion of market hogs slaughtered in Federal establishments. FSIS collected a total of 3,920 sponge samples (1,960 at pre-evisceration and 1,960 at post-chill) at 152 establishments. Only market hogs were eligible for testing in the survey. Boar or stag swine, feral swine, roaster swine, and sows were excluded from this survey.

Through the survey, FSIS gathered data concerning the percent positives and quantitative levels of selected foodborne pathogens, and microorganisms as indicators of process control (e.g., *Salmonella*, generic *Escherichia coli*, Enterobacteriaceae, coliforms, and aerobic plate counts). Additional information regarding The Nationwide Microbiological Baseline Data

Collection Program: Market Hog Survey August 2010 to August 2011 may be found at the following link: http://www.fsis.usda.gov/wps/wcm/connect/d5c7c1d6-09b5-4dcc-93ae-f3e67ff045bb/Baseline_Data_Market_Hogs_2010-2011.pdf?MOD=AJPERES.

These data collected and discussed in this document, and best practices described throughout this document will enable the Agency to work more effectively with industry to reduce the risk of foodborne pathogens in FSIS regulated products.

IV. Cross Contamination

Main routes for cross contamination:

- Airborne bacteria
- Contamination of walls or floors by splashing of contaminated fluid
- Contact with dirty surfaces (through equipment, hands, clothes

All controls in slaughter and dressing procedures should be aimed at eliminating contamination. Slaughter establishments can reduce prevalence of pathogens by conducting operations in a manner that reduces contamination. Establishments can eliminate or reduce contamination through adequate separation of carcasses, parts, and viscera during dressing, routine cleaning and disinfection of equipment and hand tools as described in 9 CFR 416.3.

In addition, establishments should use appropriate equipment and arrange equipment to prevent cross contamination of carcasses and parts. They should use equipment designed so that that it can be adequately cleaned and sanitized daily. Finally, they should ensure functional lavatories are appropriately located, with hand washing and disinfection units strategically placed on the slaughter floor as described in 9 CFR 416.2 (h).

Cross-contamination occurs when pathogens are carried throughout the plant and adhere to carcasses and meat contact surfaces. Bolton (2002) showed that there can be airborne bacterial contamination at levels up to 3.5 $\log_{10}$ CFU/m^3 within the slaughter establishment. McDermid and Lever (1996) showed that *Salmonella* can survive in aerosols at 75.2°F (24°C) and 75% humidity for periods exceeding 24 hours. These positive correlations with the environment suggests that contaminated air may be a source of carcass contamination.

Key Point:

The first and paramount rule of sanitary dressing is to avoid any contamination of edible portions of the carcass with materials such as feces, urine, hair, ingesta, milk, bile, pathological tissues or exudates, or other filth.

Scalding and singeing can greatly reduce bacteria on the skin of the hog; however, the skin is often recontaminated when the carcass passes through dehairing and polishing equipment (Yu, 1999). Polishing carcasses contaminated with feces may make this contamination invisible, allowing it to go undetected during subsequent visual inspections.

Recommended Best Practices: Cross Contamination Prevention

- **Minimize airborne contamination through effective ventilation and control of air flow**
- **Sanitize equipment and enforce employee hand washing to prevent contamination during processing**
- **Separate from the processing areas the facilities for hand washing, access to toilet facilities, and areas where clothes and footwear are changed**
- **Use walls and other separating structures, between "dirty" and "clean" processes and maximize spatial separation of activities to reduce cross-contamination**

V. Farm Rearing

Control of Salmonella begins on the farm. A review of Danish pork production has shown that *Salmonella* prevalence in the herd is a significant factor for determining the *Salmonella* prevalence and levels on carcasses (Alban and Stark, 2005). Limiting the commingling of piglets in the nursery from various sources, as well as rodent control, at the rearing farm has shown a decrease the incidence of *Salmonella* (Goldbach, 2005).

Salmonella infection in hogs may not be obvious because hogs can be asymptomatic carriers (Schwartz, 1999). There is an association between *Salmonella* positive hogs and contaminated carcasses at the end of the slaughter line (Vieira-Pinto, 2006). One study found that carcass contamination was mainly influenced by the probability that at least one hog contributing to the pool was seropositive (Baptista, et al 2010). This finding suggests the *Salmonella* carcass contamination came from the incoming hogs, and that *Salmonella* control on the farm is desirable. Other studies have shown a correlation between increased levels of *Salmonella* in hogs and the use of pelleted food (Davies, et al 1997).

Recommended Best Practices: Farm Rearing

- **Control rodents**
- **Control co-mingling of hogs and reduce human contact**
- **Use nonpelleted feed**
- **Practice good sanitation, biosecurity, and dead control**
- **Vaccinate herd for *Salmonella* where applicable**

VI. Transport

Stress during transport and slaughter is known to influence the physiological and biochemical processes in hogs (Benjamin, 2005). Stress is thought to affect the bacterial ecology of the gastrointestinal tract and the immunity of the animal, resulting in increased *Salmonella enterica* shedding (Hurd, 2003).

Rapid infection after exposure to *Salmonella* during transport (e.g., when trailers are not cleaned between loads from different sources) is a major reason for increased *Salmonella enterica* prevalence in hogs (Hurd, 2002). Hurd et al. (2005) reported increased serovar diversity of isolates obtained after slaughter compared to that of isolates from pen mates necropsied on the farm. This increase in diversity suggests that hogs may be exposed to new *S. enterica* sources after leaving the farm.

Recommended Best Practices: Transport

- **Clean transfer trailers after each use**
- **Do not mix hog herds during transportation (Boes, 2001)**

VII. Lairage

A study of hog slaughter processing concluded that the lairage is the most cost-effective stage to prevent cross-contamination that leads to rapid infection (Vander Gaag, 2004).

Prolonged transportation and holding in the lairage may induce *Salmonella* shedding by infected hogs (Alban, 2005). Several Hurd studies offer insight into the preharvest ecology of *Salmonella* during lairage.

Key Point:

Lairage is the most cost-effective stage to prevent cross contamination.

These studies suggested the following:

- Hogs become internally contaminated with *Salmonella* after leaving the farm (Hurd, et al 2001)
- Surface contamination of the holding pen reflects the quality of in-plant practices and may not be a useful measure of pre-harvest prevalence (Hurd, et al 2001)
- There is rapid infection during holding, suggesting the holding pen as an important *S.enterica* control point in the preharvest pork production chain (Hurd et. al. 2003).
- In addition to the frequent contamination of holding pens, 33.3% of hog drinking water samples were contaminated with *Salmonella.* This finding indicates that more attention to the microbiological quality of water is needed and that the water may be contaminated from the environment (Hurd, 2003)

Key Point:

It is important to remember that lairage is a critical processing step in hog slaughter that should not be overlooked. Implementation of recommended best practices can minimize or eliminate the spread of *Salmonella* at subsequent processing steps.

Recommended Best Practices: Lairage

- **Minimize the time the hogs are held in lairage (Hurd, 2001)**
- **Prevent overcrowding during time in lairage (Hurd, 2001a,b)**
- **Keep water in lairage pens fresh and change after each herd (Rostagno, 2003)**
- **Use slatted or elevated floors in lairage pens to reduce waste and water accumulation**
- **Maintain lairage pens in order to prevent conditions that could injure animals**
- **Avoid mixing of herds (Borch, 1996; Alban, 2005)**
- **Disinfect lairage pens and alley ways, between herds, using chlorinated alkaline detergent followed by disinfection with a quarternary ammonium solution (Dehalle, 2008)**
- **Ensure that hogs are washed clean (pen shower) and dry enough to preclude dripping at the time of stunning**
- **Segregate *Salmonella* positive herds and process them at the end the production day (Alban, 2005;Boes, 2001)**

VIII. Stunning

Carbon dioxide (CO_2) and the electro narcosis stunning methods have no effect on carcass microbiology (Dehalle, 2008). Appropriate stunning methods are required for an establishment to be in compliance with the Humane Methods of Slaughter Act (HMSA).

IX. Slaughter/Bleeding

The bleeding process results in a significant accumulation of body fluids, feces, and dirt on walls and floor of the area and is a significant source of cross contamination for *Salmonella* (Bolton, 2002).

A study showed that stick knives have tested positive for *Salmonella* and may be a source of cross-contamination (Bottledoorn, 2003), suggesting that sanitation of knives is critical. Efficiency and control of knife use is important to prevent wounds that are too deep. Deep wounds may penetrate the oropharnyx or may allow introduction of scald water and pathogens including *Salmonella,* into the pleural cavity.

Key Point:

The bleeding process is a significant source of cross-contamination for *Salmonella.*

X. Scalding

Vertical scalding using steam may improve the bacteriological quality of the meat, prevent bacterial contamination of lungs, and reduce muscular degeneration and development of pale, soft, exudative muscle (PSE) because the internal temperature of the meat does not exceed 5°F (41°C) (Gracey, 1992). Vertical steam scalding reduces operating costs if the cooling water from the condenser in the steam tunnel is used to flush the carcasses during the de-hairing process.

Scalding may be used as a critical control point (CCP) in a HACCP system (Bolton, 2002; Hald, 1999) if the temperature of the scalding water/steam and the duration is adequate.
The cleanliness of the hogs and the status of the scald water were factors significantly associated with *Salmonella* on the carcasses at the end of the slaughter process (Letellier, 2009).

Key Point:

Scalding may be used as a critical control point in a HACCP system if the temperature of the scald water or steam and duration of scald are adequate.

Recommended Best Practices: Scalding

- **Evacuate feces from the rectum or implement an anus bunging system (coning)**
- **Wash the evacuated carcass before scalding**
- **Scalding water should be 145 °F (62°C) for 5 minutes**
- **Maintain sanitary conditions. Ensure that the scalder is easy to clean and in good condition and repair.**
  Drain and clean the scalder daily. Pay particular attention to weld sites and rough, scratched areas in the interior of the tank to ensure proper cleaning
- **Remove or prevent accumulations of hair and protein from the scalder and de-hairing machine both before and during operations. Control condensation as needed to maintain sanitary conditions. Recirculation of water may affect accumulation of hair and residue and control temperature fluctuations**
- **Maintain a clean supply of water. Change the scald water frequently to prevent organic load build up**

Recommended Best Practices: Scalding

- **Use a counter current application (fresh or recirculated scald water that flows into the scalder in an opposite direction from that of the carcasses) to increase heating efficiency and water cleanliness**
- **The stick wound should be promptly trimmed, and preferably immediately after scalding. The trimmings should be discarded**
- **A vertical steam scald at 212°F (100°C) allows for a constant supply of clean steam and prevents the organic load which would accumulate if a water system was used**
- **Add an anti-foaming agent to the scald water to reduce organic load build up in foam**

XI. De-hairing

Care is needed when using a de-hairing machine in order to prevent recontamination and increases in bacterial load (Morgan, 1987; Gill and Jones, 1995; Gill and Bryant, 1993; Davies, 1999 27; Yu, 1999; FRPERC 2007). *Salmonella* has been detected in air samples at the locations of de-hairing and evisceration operations (Pearce, 2005).

Recommended Best Practices: De-hairing

- **Clean and disinfect de-hairing equipment, preferably using a clean-in-place (CIP) system which may be applied on an ongoing basis throughout production**
- **At the end of the production day, remove all organic material and debris from de-hairing equipment by power hosing with water at a pressure of 290 to 435 psi. A layer of alkaline detergent should then be applied to the equipment for 15-20 minutes in order to remove any organic material prior to sanitation of the equipment using a quaternary ammonia or similar disinfectant (Bolton, 2002)**
- **Use water between140° to 144°F (60 to 62°C) in the de-hairing machine if the water is not chemically treated (7 ICMSF, 1998)**
- **If possible, prior to de-hairing evaluate methods to prevent fecal voiding (Bolton, 2002). Have in place procedures to clean contaminated carcasses that void fecal material after de-hairing and prior to gambrelling and rehanging.**
- **Pasteurize hog carcasses using hot water sheets 185°F (85°C) or higher for 20 seconds after de-hairing. This has been shown to reduce contamination (Bolton, 2002; McMullen, 2000)**
- **For hand shaving, use an extremely sharp knife. Prevent cutting through the skin in order to reduce introducing bacteria into the interior of the carcass**

XII. Gambrelling

Recommended Best Practices: Gambrelling

- **Assure carcasses are not recontaminated on the gambrel table by hogs that evacuate bowels post de-hairing.**

XIII. Steam/Hot Water Vacuuming

The decontamination of pork carcasses by steam and lactic acid reduced the surface microbial counts immediately after treatment and retarded microbial growth during storage. Such treatment can be used to prolong the shelf-life and to increase the safety of pork carcasses. (Pipek et al. 2006)

Recommended Best Practices: Steam/Hot Water Vacuuming

- **Assure carcasses are not recontaminated on the gambrel table by hogs that evacuate bowels post de-hairing**
- **Monitor equipment temperature, pressure, and nozzle (Pipek et al, 2006)**
- **Vacuum carcasses from top to bottom using 90-95 ° F (35 °C) steam (Pipek,et al 2006)**
- **Clean the equipment frequently on a regular preventative maintenance schedule**
- **Apply steam vacuuming to carcasses after de-hairing, singeing, or polishing**
- **Use a 2% lactic acid solution at 131°F (55°C) for more than 60 seconds, 13-23psi (VanNetten et al.1995**

XIV. Singeing

Singeing has been identified as a significant step for reducing microbial contamination on the surface of hog carcasses, including *Salmonella* (James, 2007; Bolton, 2002; Pearce, 2004; Alban and Stark, 2005). Various studies have shown that singeing achieves a 2.5-3.0 $\log_{10}$ CFU/cm^2 reduction in total microbial load (Bolton, 2002; Pearce, 2004) and a reduction of *Salmonella* incidence from 7% to 0% (Pearce, 2004). A study by Dehalle showed that a single singeing process can decrease the APC (aerobic plate count) 2.2 to 2.5 $\log_{10}$ CFU/cm^2.

Key Point:

Singeing has been identified as a significant step for reducing microbial contamination on the surfaces of hog carcasses, including *Salmonella*.

Recommended Best Practices: Singeing

- **Use a full (multiple heat sources) singe process**
- **Ensure that the surface carcass temperature reaches 212°F (100°C)**

XV. Polishing

Polishing is a primary mode of pork carcass recontamination following reductions that were achieved during singeing (James, 2007; Bolton, 2002; Snijders, 1984; Gill, 1995; Hald, 1999). Any surviving bacteria are mechanically disseminated by stainless steel scrapers or nylon brushes used in polishing (Delhalle, 2008). Polishers must be cleaned thoroughly because they harbor and allow bacteria to multiply to high levels (Borsch, 1996; Huis in't Veld, 1992).

Key Point:

Polishing is a primary mode of pork carcass recontamination following reductions that were achieved during singeing.

Recommended Best Practices: Polishing

- **Use high pressure water jets instead of flail or whip wet polisher**
- **Thoroughly and frequently clean the polishing equipment**
- **If singeing is efficient, the polishing process may be replaced with a pressurized, 185°F (85°C) or higher hot water wash, improving carcass decontamination rather than possible recontamination during polishing. (Gill, 1995, 1998; Van Netten, 1995; Spescha, 2006)**
- **Add an additional singeing step, after polishing, to reduce contamination introduced by polishing (Spescha, 2006, Dehalle, 2008); Consider whether carcasses have been adequately reconditioned in a sanitary manner, if contaminated by feces voided during the gambrelling step**

XVI. Knife Trimming

Before treating carcasses with a pre-evisceration rinse or spray, a measure should be in place to prevent visibly contaminated carcasses from being sprayed or rinsed. If steam or hot water vacuuming is not available, knife trimming can be used to remove fecal contamination and other dressing defects. Knife trimming reduces the volume of contamination that might otherwise be diluted by washing after singeing.

XVII. Pre-evisceration Carcass Rinse or Spray

A listing of suitable compounds that can be used for pre-evisceration rinsing or spraying is detailed in FSIS Directive 7120.1.

Additional information regarding antimicrobial compounds can be found at the following web sites:
http://foodsafety.psu.edu/movies/carcass.html
http://foodsafety.psu.edu/movies/intervention%20booklet%202005.pdf.

Pre- evisceration Rinse or Spray

- **Use water at a temperature greater than 160°F (71.1°C)**
- **Trim open abscesses, septic bruises, parasites, and parasitic lesions before the carcass enters the cabinet**
- **If pressure is used to spray, do not exceed 100 psi to prevent driving contamination into the tissue**
- **Monitor concentrations and temperatures regularly to verify effectiveness**
- **Minimize overspray of water or solution from the cabinet**
- **Larger operations should consider using stainless steel cabinets with an arbor of spray nozzles**

Pre- evisceration Rinse or Spray

- **Apply organic acids with a hand spray applicator assuring the carcass is totally covered**
- **Consider using a post-evisceration rinse or spray to further reduce carcass contamination**
- **Verify that the cabinet is used in a manner that prevents cross contamination of adjacent carcasse; Carcasses should not be touching prior to final inspection**

XVIII. Head Washing/Head Dropping

Recommended Best Practices: Head Washing/ Head Dropping

- **Flush the oral cavity removing ingesta, bile, or other contaminants before head dropping and head inspection**
- **Sanitize knives and head dropping equipment between carcasses and whenever sectioning of the gullet occurs**
- **Be aware of potential contamination of the head, neck, and carcass by knives or equipment after incision of the oral-pharyngeal cavity or from exposure to fresh stomach contents when dropping heads and processing of head and cheek meat**

XIX. Bung Isolation

Recommended Best Practices: Bung Isolation

- **Tie bung, cut free from surrounding tissues with a single incision, and cover area with a protective covering**
- **During separation prevent contact of bung with carcass or with viscera. Secure bag with tie or clip**
- **Ensure employee hygiene and use of personal protective equipment (gloves and aprons) (McEvoy, 2003b, Edwards and Fund, 2006)**
- **Immediately remove any contamination that results from bunging**
- **If possible, use an automated bunging system called "bung guns" instead of manual bung tying. An automated bunging system will reduce cross-contamination, by going around the anus and evacuating the rectum (Sheridan, 1998)**
- **Sanitize bung guns, knives, and hooks between each carcass**
- **Prevent contaminated water from dripping down the back of the carcass**

XX. Evisceration

Recommended Best Practices: Evisceration

- **Remove all hair, scurf, and dirt from the hooves and the carcass and thoroughly wash the carcass before evisceration (9 CFR 310.11)**
- **Sanitary dressing guidelines for beef may be applied to swine**
- **To prevent contamination of the carcass or viscera, tie the rectum before evisceration. Remove the pluck with gullet and viscera attached (so there is no leakage)**
- **Only skilled, experienced individuals should perform the evisceration; Experienced individuals are needed at higher line speeds**
- **Avoid cutting or rupturing the gut.**
  The critical operations are: cutting around the rectum, removal of the intestinal tract, and removal of the pluck system (Alban and Stark, 2005)
- **Take care to avoid cross-contamination, which may occur when carcass splitting saw blades come in contact with the spinal column or throat (Dehalle, 2008)**
- **Remove carcasses with visual contamination or bruising for reconditioning (knife trimming or steam vacuuming) before carcass splitting**
- **Disinfect carcass splitting equipment after each use (9 CFR 416.3, 416.4).**

XXI. Pre-chill Final Rinse/Hot Rinse/Steam Pasteurization

Recommended Best Practices: Pre-chill Final Rinse/Hot Rinse/Steam Pasteurization

- **When a contaminated carcass is not adequately cleaned before the final wash, the carcass should be diverted to a holding rail until cleaned**
- **Clean the contaminated carcasses by removing visible contamination by trimming or steam or hot-water vacuuming prior to final inspection and final washing**
- **Rinse carcasses from the top down**
- **Minimize any splash onto other carcasses**
- **When utilizing a thermal pasteurization system, deliver water or steam to the entire surface of the carcass at a temperature of at least 165°F (73.9°C).**
- **Pressure should not be high enough to drive contamination into the tissue**
- **Small operations may use cold water to wash carcasses; Improve decontamination by adding chemicals such as chlorine or trisodium phosphate (Bolton 2002)**
- **A pressurized diluted 2 to 3% lactic acid or acetic acid is recommended (McMullen, 2000). Consider careful treatment of necks and inside jowls when the head is separated from the carcass**
- **Monitor drains to ensure they are working properly and prevent backup that may result in carcass and equipment contamination**

XXII. Spray Chilling

Recommended Best Practices: Spray Chilling

- **Spray chill carcasses using an organic spray 2 days prior to fabrication to maximize reduction of *Salmonella* (Algino, 2009)**
- **Maintain the cooler at a temperature that ensures carcasses will have an internal temperature of 40°F (4.4°C) 24 hours after being put in the cooler**

XXIII. Carcass Fabrication

Recommended Best Practices: Carcass Fabrication

- **Apply organic acid antimicrobial treatment**
- **Maintain boning and fabrication rooms at 50°F (10°C) or less**
- **Maintain fabrication area and equipment in a sanitary condition**

XXIV. Packaging/Finished Product Storage and Transport

Recommended Best Practices: Packaging/Finished Product Storage and Transport

- **Storage room and transportation vehicle temperature should be maintained at 40°F (4.4°C) or less**
- **Maintain Internal meat temperature during storage at 40°F (4.4°C) or less**
- **Monitor and document temperature of storage room, vehicle, and meat**

XXV. Validation

Validation is the process of demonstrating that the HACCP system as designed can adequately control identified hazards to produce a safe, unadulterated product.

Examples of some controls that would require validation are CCPs, pre-requisite program interventions preventing a hazard from being likely to occur, and product formulations when the formulation contributes to the safety of the product.

There has been much confusion about which HACCP activities are on-going verification and which are initial validation. This confusion has been magnified by the fact that the NACMCF definition of the HACCP principle verification includes validation. Many agree that validation should be a distinct function from verification (Scott and Stevenson, 2006).

Key Point:

There are two distinct elements to validation:

1. **The scientific or technical support for the HACCP system design and;**
2. **The initial practical in plant demonstration proving the HACCP system can perform as expected (execution)**

90 calendar days of initial validation takes place upon completion of the hazard analysis and development of the HACCP system. This period provides an opportunity to check the validity or adequacy of the HACCP system. Establishments are to conduct validation activities during their initial experience with a new HACCP system. Establishments are required to complete the initial validation of the new HACCP plan in accordance with 9 CFR 417.4 during a period not to exceed 90 calendar days after the date the new process is used to produce product for distribution in commerce.
During these 90 calendar days, an establishment gathers data from its monitoring and on-going verification activities at an increased frequency than listed in the HACCP plan and gathers additional data to demonstrate that the process is being executed effectively. During this period an establishment should be reviewing these data and making modifications to its system as necessary. Many agree that validation should be a distinct function from verification

Following the 90 calendar day period of initial validation, an establishment uses its findings during the initial validation period to fully implement its system and solidify its monitoring and on-going verification procedures and frequencies. The establishment then continues on a daily basis to perform monitoring and verification activities to ensure that the HACCP plan continues to be implemented properly.
Ongoing verification activities include but are not limited to: the calibration of process-monitoring instruments; direct observation of monitoring activities and corrective actions; and the review of records generated and maintained in accordance with 417.5(a)(3). During the annual reassessment, FSIS recommends that establishments review specific food safety related records generated during ongoing verification that demonstrate that their HACCP systems are adequate (i.e., test results and monitoring of critical operational parameters). Additional information on validation can be found in the FSIS Compliance Guideline for HACCP Systems Validation at:
http://www.fsis.usda.gov/wps/wcm/connect/a6a16ac5-93e0-46dc-986a-557930d2209f/HACCP_Systems_Validation_Draft_Guidance_0412.pdf?MOD=AJPERES.

XXVI. Process Control Verification

Process control is a procedure or set of procedures designed to provide control of the establishment's operating conditions that are necessary for the production of safe and wholesome food.

The goal of process control in a slaughter establishment is to minimize microbial contamination of the carcasses, to reduce bacterial pathogens that may be present and injurious to health, to control the proliferation of any remaining micro-organisms, and to prevent recontamination.

Process control procedures are likely to include decontamination of carcasses, adequate sanitary dressing practices, antimicrobial intervention treatments, and implementation of best practices described throughout this compliance guide. Establishments that fail to control these procedures and treatments create the potential for contamination of carcasses and products.

Establishments can verify the effectiveness of their process control procedures by conducting:

- process mapping and;
- conducting on-going verification activities, such as microbiological sampling and testing utilizing indicator organisms.

Process mapping is a useful challenge study tool. Process mapping entails conducting microbial sampling at selected points in the process where contamination levels can be assessed.
The assessment measures microbiological loads on carcasses against a specific target organism or class of organisms. Process mapping provides a baseline for assessing the effectiveness of certain interventions as well as the effectiveness of the overall food safety system. Process mapping shows areas where immediate improvements can be made or where there is a need for process adjustments.
A process mapping (testing) protocol could include procedures for obtaining multiple samples after each processing step or slaughter period (shift). Plotting these test results can then be used as a map of the microbial reduction at each intervention step in the system.

Key Points:

- **Process mapping entails conducting microbial sampling at selected points in the process where contamination levels can be assessed.**
- **Process mapping shows areas where immediate improvements can be made or where there is a need for process adjustments.**

XXVII. Process Control Verification Using Indicator Organisms As Performance Criteria

Microbiological sampling programs within establishments can include testing for indicator organisms. Indicator organisms are analyzed to predict the distribution, number, and response of specific pathogenic organisms on a particular product as it travels through a HACCP system.

Testing for indicator organisms is less costly than testing for pathogenic bacteria. Also, indicator organisms are easier to detect and quantify.

Testing for indicator organisms is a valuable tool to monitor actual in-plant processes and determine whether a process is in control. Establishments may choose from a variety of indicator organisms to measure microbial contamination and determine process control. Examples of indicator organisms that may be suitable measures of fecal contamination include aerobic plate count (APC), *Enterobacteriaceae*, Total coliforms, and Generic *E. coli*.

If an establishment does not have its own indicator organism data, it can use the process control limits developed from the FSIS Nationwide Market Hogs Microbiological Baseline Survey (MHBS) testing results (2010-2011) to help achieve this goal, provide information that is easier to detect and quantify, and facilitate daily verification activities. During the MHBS, FSIS collected samples from two points during processing: pre-evisceration and post-chill. Pre-evisceration refers to the location early in the process prior to evisceration of the hog. Post-chill refers to a later point in the process after carcasses are chilled; all interventions completed, and before the hog carcasses enter coolers.

Key Points:

Advantages of using indicator organisms:

- **Less costly**
- **Easier to detect and quantify**
- **Valuable tool to monitor in plant processes**

The information in Table 1 below was derived from the FSIS Nationwide Market Hog Microbiological Baseline Survey (MHBS) for specific indicator organism limits that correspond to the 80th percentile. FSIS compared the presence and levels of specific microbiological targets to determine whether significant differences existed between samples taken at pre-evisceration and post-chill. Percentiles represent the percent of establishments that are below the associated number in the distribution of average bacteria indicators per plant. An establishment may use the indicator organism limits in the Table 1 to verify that the establishment is exercising process control. For example, the table demonstrates that if an establishment has APC levels above 790 CFU/cm^2 at post chill, its process is most likely out of control, and the establishment should immediately take corrective action to bring its process back under control.
A prudent establishment should aim for results below those limits listed for each indicator organism at pre-evisceration and post chill locations. Indicator organism results below control limits shown in Table 1 indicate that the process is in control.
For example, APC levels below 790 CFU/cm^2 demonstrates effective process control.
FSIS recommends that the establishment plot data over time to determine whether its overall processes are in control and to determine the variability in its food safety system.

The establishment should take appropriate actions if it determines that its process is not in control.

Table 1: Indicator Organism Criteria Limits for Market Hogs

Indicator Organism	**APCs**		***Enterobacteriaceae***		**Total Coliforms**		***E. coli***	
Average CFU/cm²	Pre-evisceration	Post-chill	Pre-evisceration	Post-chill	Pre-evisceration	Post-chill	Pre-evisceration	Post-chill
	4200000	790	8,300	110	5,500	35	3,800	30
Distribution Percentile	80%		80%		80%		80%	

Given that samples collected per establishment in the MHBS were limited, and the variation within individual establishments was high, the control limits in the table are approximations.

Testing for indicator organisms is a valuable tool for assessing consistent process control within an establishment and is less costly than testing for *Salmonella*. Moreover, indicator organisms are generally easier to quantify than *Salmonella*. Nonetheless, a prudent establishment would adopt a testing program that includes both indicator organisms and testing for the pathogen *Salmonella* at an established frequency as part of its on-going in plant verification program. The indicator organisms would provide ongoing evidence of control, while periodic testing for the pathogen *Salmonella* would verify that the process is successfully addressing the pathogen. Establishments may use their own sampling data if there is adequate statistical rigor to establish statistical process controls action levels. Many small and very small establishments may not have resources for a program that provides for a sampling frequency to determine statistical process control action levels. Therefore, an establishment can also use the estimated national prevalence of 1.66% for *Salmonella* calculated from MHBS to assess establishment *Salmonella* sampling results to determine whether their processes are in control. If aggregated test results over time for an establishment are above the national prevalence estimate of 1.66%, it raises questions about the adequacy of process control within that establishment. Additional information on the national prevalence estimate can be found in the baseline report at: http://www.fsis.usda.gov/wps/wcm/connect/d5c7c1d6-09b5-4dcc-93ae-f3e67ff045bb/Baseline_Data_Market_Hogs_2010-2011.pdf?MOD=AJPERES.
The indicator organisms would provide ongoing evidence of control, while periodic testing for *Salmonella* would verify that the process is sucessfully addressing *Salmonella.*

XXVIII. New Technologies

FSIS recognizes that new technologies provide opportunities to improve and strengthen cost effective process controls.

The Agency strongly recommends that all establishments be aware of new techniques, chemicals, and machinery that may be utilized to improve their ability to produce wholesome products. FSIS has reviewed submitted protocols and listed these new technologies on the FSIS Web site. For detailed information on particular technology, interested parties should contact the listed new technology provider or manufacturer's web site. This list is at: http://www.fsis.usda.gov/Regulations/New_Technology_Table_Feb_06/index.asp.

> ***Key Point:***
>
> **New technologies provide opportunities to improve and strengthen cost effective process controls.**

In addition, FSIS has funded Cooperative Agreement studies. From studies completed in 2003, FSIS identified technologies that may reduce levels of *Salmonella*. These technologies may be cost-effective for small and very small plants. A list of these completed studies on new technology can be found at: http://www.fsis.usda.gov/regulations_&_policies/Technologies_Applicable_for_Small_Very_Small_Plants_FY2003/index.asp.

XXIX. Information from Food Safety Assessments (FSAs)

An FSA is a comprehensive evaluation of an establishment's food safety system that assesses the establishment's sanitation controls, compliance with microbiological performance criteria, adequacy of slaughter house and processing plant Hazard Analysis and Critical Control Point (HACCP) systems, the design and operation of its prerequisite programs (including sanitary dressing procedures), and its response to food safety control deviations. In 2009, FSIS began prioritizing the scheduling of FSAs based on public health decision criteria, in addition to traditional event-based scheduling. FSIS Directive 5100.4 Prioritized Scheduling of Food Safety Assessments (FSAs) Using the Public Health Information System (PHIS), provides the decision criteria that FSIS uses to schedule FSAs.

An establishment that meets one or more of the decision criteria under any of the priority levels provided in Table 1 of FSIS Directive 5100.4 will receive a “for cause” FSA. A “for cause” FSA is one that is prompted by a positive sample result, production and shipment of adulterated product, or any other high priority food safety related incident. An establishment’s failure to meet the *Salmonella* Performance standard is one of the public health decision criteria that will result in a “for cause” FSA.
Since 2009, there has been one FSA conducted by FSIS in response to an establishment’s failure to meet the *Salmonella* Performance Standards for market hogs. FSIS completed a *Salmonella* set for market hogs at this establishment on March 25, 2010, and found 7 positives in the sample set (one over the limit of 6). This finding resulted in a “for cause” FSA being conducted at the establishment. In response to the FSA findings, the establishment implemented the following corrective actions:

- Increased lactic acid concentration from 2 to 5% to a consistent 4.5 % level sprayed on carcasses just prior to entering the cooler
- Targeted Inspexx (antimicrobial) at 200 ppm (instead of 100 – 200ppm)
- Retrained employees in GMPs
- Reviewed carcass chilling procedures and sanitary carcass dressing procedures
- Placed hog carcass coolers on a regular cleaning schedule
- Collected knives used on the kill floor at the end of the shift and implemented cleaning by a contract sanitation company.

The establishment completed its second sample set on July 23, 2010, and passed with 4 positives in the set.

XXX. Conclusion

Microbial contamination in the slaughter house environment can start with the delivery of *Salmonella* positive hogs. However, there is significant scientific evidence that a large number of hogs are exposed to *Salmonella* during lariage. Such awareness of potentially significant areas of contamination can serve as reinforcement to reduce *Salmonella* during harvest. Studies have also shown that improved pre-harvest sanitation can reduce the levels of *Salmonella* exposure. Sanitary maintenance of slaughter house equipment, good slaughtering practices, and effective washing and disinfection of equipment and materials at critical steps are critical to reducing *Salmonella* contamination. If sanitary conditions are not maintained throughout slaughter and processing, the major reductions in microbial load noted at some stages of the process can be offset by cross-contamination or recontamination at subsequent stages of the process. Decreasing the level of *Salmonella* during slaughter and processing can decrease the number of human cases of salmonellosis from pork consumption by 75% (Miller, 2005).

FSIS recommends that intervention and control strategies be formulated based on a combination of measures that are both practical and economically feasible. A multi-factorial infection such as *Salmonella* requires a multi-level approach of intervention and control. Appropriate modifications of establishment operations based on information provided in this guidance should reduce the levels of *Salmonella* in slaughter steps.

Attachment 1

Supplemental Information

Controlling Parasitic Hazards in Market Hogs:
(*Trichinella spiralis* and *Toxoplasma gondii*)

Trichinella spiralis (*T. spiralis*) and *Toxoplasma gondii* (*T. gondii*) are parasites that infect both humans and warm-blooded animals.

Trichina is a generic term that refers to *Trichinella*, and the disease caused by this parasite is referred to as trichinellosis. Humans can become infected with *T. spiralis* by consuming encysted larvae in the muscle tissue of an infected animal. A common source of trichinellosis in humans is the consumption of undercooked pork. Pigs are the primary host for *T. spiralis* (Hill et al., 2012). Felids (cat family) are the primary host for *T. gondii*, and they can contaminate the environment by excreting the oocyst in their feces (Jone et al., 2012). Domestic food animals, including pigs, can be infected by *T. gondii*, and infected animals harbor *T. gondii* tissue cysts. Human can become infected by ingesting tissue cysts from raw or undercooked meat (Hill et al., 2010).

Trichinella spiralis (T. spiralis) and Toxoplasma gondii (T. gondii) are parasites that infect both humans and warm-blooded animals.

Over the past 20 years, the occurrence of *T. spiralis* infection in humans and pigs has decreased significantly in the U.S., although sporadic outbreaks still persist (Burke et al., 2008). However, the perception that pork may be infected with *T. spiralis* continues to be a food safety concern with some consumers. One of the most common parasitic infections in humans is toxoplasmosis. *Toxoplasma gondii* is the second leading cause of foodborne illnesses resulting in deaths (24%), accounting for an estimated 327 deaths annually. *Toxoplasma* is also the fourth leading cause of foodborne illnesses resulting in hospitalizations (8%), accounting for an estimated 4,428 hospitalizations annually (Scallan et al., 2011).

Establishments that produce pork products should consider whether their suppliers have taken the necessary measures to prevent *Trichinella* infection in their herds.

Pre-harvest management practices in the U.S. pork industry should include the recommended best practices described below:

Recommended Best Practices: Pre-harvest practices:

- **Do not feed table scraps, uncooked waste products, animal carcasses, or animal waste products contaminated with trichina**
- **Prevent access to rodents and wildlife infected with *T. Gondi*, or to environmental contamination with cat feces such as soil, grass, feed, or water contamination (Jones et al., 2012)**
- **Prevent exposure to rodents or other wildlife infected with Trichina; Rodents can serve as a reservoir host for *Trichinella***
- **Establish and maintain an effective rodent control program**
- **Prevent cannibalism among hogs within an infected herd**

Recommended Best Practices: Slaughter

- **Obtain pork from suppliers with trichina-control programs**

Trichinella infection can also be controlled by post-slaughter processing interventions to inactivate the parasite (i.e., heating, freezing, irradiation, and high pressure processing). Participation by swine producers in the U.S. Trichinae Certification Program is an alternative to controlling *Trichinella* infection in their herds. The U.S. Trichinae Certification Program is a pork safety program that provides documentation of swine production management practices that reduce, eliminate, or avoid the risk of exposure of swine to zoonotic parasite *T. spiralis* (http://www.aphis.usda.gov/vs/trichinae). This is a voluntary program for those producers, slaughter facilities, and other persons that handle or process swine from pork production sites that have been certified under the program. The standards of this program establish a set of criteria that enable producers to market swine that are not considered a risk to human health because of exposure to *T. spiralis*. These program standards were developed as a cooperative effort of the USDA agencies (Animal and Plant Health Inspection Service [APHIS], Agricultural Research Service [ARS], Cooperative States Research, Education and Extension Service [CSREES], Food Safety and Inspection Service [FSIS]) the National Pork Producers Council [NPPC], and the pork processing industry (USDA/APHIS, 2008).

Recommended Best Practices: Post-Slaughter Processing Interventions

- **Heating**
- **Freezing**
- **Multi-Hurdle Steps (drying, curing*, salting, fermenting)**
- **Irradiation**
- **High pressure processing (HPP)**

9 CFR 318.10 - Prescribes the treatment of pork and products containing pork to destroy trichinae.
*The effectiveness of curing to eliminate T. spiralis 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. Therefore, curing alone is not recommended as a post-slaughter intervention (Porto-Fett et al., 2010).

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). In the U.S., the prevalence of *Toxoplasma* in confinement raised market hogs is approximately 2.7 % (Hill et al., 2010). For hogs raised on pastures, the prevalence has been reported to be between 50-100% (Gamble et al., 2000). The risk of *Toxoplasma* infection is significantly increased in pasture raised hogs that have access to rodents and wildlife infected with *T. gondii*or to environmental contamination with cat feces, such as soil, grass, feed, or water contamination (Jones et al., 2012).

Feral pigs are also reservoirs of infection for *Trichinella* and *Toxoplasma* for non-biosecure (or non-confinement) reared domestic hogs. Raising pigs outdoors poses a major risk for hogs being infected with *Trichinella* and *Toxoplasma* because it increases exposure to potentially infected reservoir hosts and to soil contaminated with *Toxoplasma* cysts (Hill et al., 2012; Gamble et al., 2000; Pyburn et al., 2005; Hill et al., 2010).

The risk of *Trichinella* and *Toxoplasma* infection in market hogs can be substantially reduced by employing swine production practices that eliminate the sources of exposures of these parasitic hazards, thereby reducing the likelihood of human infection from consumption of pork infected with *Trichinella* and *Toxoplasma*.

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