The U.S. Trichinae Certification Program

Pyburn, D. a (1), Gamble, H. (2), Anderson, L. (1), Miller, L. (1)

(1) USDA APHIS, 4700 River Road, Riverdale, MD, USA, 20737
(2) National Academy of Sciences, 2001 Wisconsin Ave. NW, GR322A, Washington, DC, USA 20007
*corresponding author: David.G.Pyburn@aphis.usda.gov

Abstract
In the United States, the prevalence of Trichinella in pigs has dropped sharply over the past 50 years as a result of changes in swine production practices. Because modern pork-production systems have all but eliminated Trichinella as a food-safety risk, the U.S. has developed certification as an alternative to individual carcass testing to assure pork safety.

The U.S. Trichinae Certification Program, initiated as a pilot in 1997 and established as an official U.S. Department of Agriculture (USDA) program in 2008, is based on scientific knowledge of Trichinella spp. epidemiology and numerous studies demonstrating that adherence to specific "good production practices" minimize pig exposure to the zoonotic parasite.

Under the program, three USDA agencies (the Animal and Plant Health Inspection Service [APHIS], the Food Safety and Inspection Service [FSIS], and the Agricultural Marketing Service [AMS]) collaborate to verify that certified pork-production sites manage and produce pigs according to the requirements of the program's "good production practices." Production sites participating in the program are certified as "trichinace-safe" if sanctioned good production practices are followed. The USDA also verifies the identity of pork derived from pigs from certified production sites through slaughter and processing.

Introduction
Prevention of human trichinellosis is a public health goal and there are numerous international standards for testing and treating pork to prevent human infection. Individual carcass testing has been an effective method for preventing clinical trichinellosis in humans in many countries, but the cost of testing is substantial (Pozio, 1998). In developed countries, modern pork production systems have all but eliminated trichinellosis as a food safety risk. In recognition of this, alternatives to individual carcass testing are now being explored for documentation of pork safety. Groups including the International Commission on Trichinellosis (ICT), the Office Internationale des Epizooties (OIE), and the European Union Veterinary Working Group are considering these alternatives. It is with this background that the United States Department of Agriculture (USDA) and the U.S. pork industry have developed the U.S. Trichinae Certification Program.

Food safety is a high priority for the U.S. government and the U.S. pork industry. In an effort to ensure the safety of U.S. pork, research projects have been ongoing over the last ten plus years to identify and control the risk factors for trichinae at the farm level. The USDA has worked with the National Pork Board and the pork processing industry to utilize knowledge from this research to develop a federal regulatory program, the U.S. Trichinae Certification Program. The U.S. Trichinae Certification Program provides documentation of pork production management practices that minimize the risk of exposure of pigs to Trichinella spiralis. It is an alternative to individual carcass testing that can be used when pigs are raised in production systems where risk of exposure to T. spiralis has been eliminated.
Materials and Methods
Knowledge of risk factors for exposure of swine to *Trichinella spiralis* were used to develop an objective audit of on-farm production practices that could be applied to pork production sites (Gamble and Bush 1998, Gamble et al. 2000, and van Knapen 2000). The on-farm audit included aspects of farm management, bio-security, feed and feed storage, rodent control programs, and general hygiene. In a pilot study, objective measures of these good production practices were obtained through review of production records and an inspection of the production site. Within the pilot, 461 production site audits were performed by veterinary practitioners. These veterinarians had previously been trained on auditing procedures, *Trichinella* risk factor identification, and *Trichinella* Good Production Practices (Pyburn 2002, Trichinella Certification Pilot Program Standards 2001 and Trichinella Certification Pilot Program Auditor Handbook 2001). Site specific trichinae certification was granted or denied each of the pork production sites dependent upon the outcome of the audit. Program sites were audited on a regular schedule as established by the Trichinella Certification Pilot Program Pilot Program Standards. In the same pilot study, verification testing of swine raised on certified sites was subsequently performed at slaughter using an ELISA test. Verification testing is random testing of a statistically valid sample of swine from Trichinella Certified production sites. This testing is performed to verify that the swine coming from Trichinella Certified production sites are free of *Trichinella*. Verification testing of swine from audited production sites was performed by trained laboratory technicians at the slaughter plant.

As a result of the pilot it has been determined that the following Good Production Practices will be employed and audited in the now officially established Trichinella Certification Program:

1. The movement of all non-breeding swine 5 weeks of age or older into or from the pork production site must be documented in an animal movement record that ensures that all such swine moved into or from the site can be subsequently traced back to that site, or to any previous site (if applicable).
2. All non-breeding swine entering a site must have originated from another certified production site, except for non-breeding swine less than 5 weeks of age may have originated from either a certified or noncertified production site. The animal movement record must include the PIN of the certified production site from which the swine originated. If the swine are less than 5 weeks of age and come from a noncertified site, then the animal movement record must provide the name and full address of the noncertified site where the swine originated.
3. Feed or feed ingredients from offsite sources that are used at the site must meet good manufacturing practices or other quality assurance standards recognized by the feed industry. The adherence to good manufacturing practices or other quality assurance standards must be documented in a feed mill quality assurance affidavit.
4. Swine at the site must be housed and fed in a confinement unit. The confinement unit, feed preparation and storage areas, and office areas and connecting hallways at the site must be inspected regularly and found free of signs of rodent and wildlife activity. Any movable harborage (exterior or interior) on the site that is not necessary to the day-to-day operation of the site must be removed. Harborage that cannot be removed or is movable but necessary to the day-to-day operation of the site must be checked for signs of rodent or wildlife activity. In addition, domesticated animals, including pets such as dogs and cats, must be excluded from the confinement unit and feed preparation and storage areas at the site. Exterior rodent bait stations and/or traps must be placed around the perimeter of the confinement unit. Exterior rodent bait stations and/or traps also must be placed around areas of potential rodent entry into the confinement unit. Interior rodent bait stations and/or traps must be placed so that swine will not come in contact with the bait or trap. Rodent bait stations and/or traps also must be placed near exterior or interior harborage on the site that cannot be removed or that is movable but necessary to the day-to-day operation of the site. In all instances, rodent bait stations must be intact, systematically maintained, and contain fresh bait that consists of an EPA-registered rodenticide formulation that is applied according to its label. In addition, a sterile zone must be maintained around the perimeter of the confinement unit. The sterile zone must be devoid of any harborage or feed or water sources that could attract rodents or wildlife, but must contain rodent bait stations and/or rodent traps. The sterile zone also must be devoid of any vegetation unless it is
decorative vegetation that is well maintained. A sterile zone with decorative vegetation will require increased rodent control measures. The producer must provide documentation of rodent control practices by maintaining at the site an up-to-date rodent control logbook with a site diagram and other recordkeeping evidencing implementation of rodent control measures, which can include documents provided by a pest control operator.

5. Feed or feed ingredients stored at the site must be prepared, maintained, and handled in a manner that protects the feed or feed ingredients from possible exposure to or contamination by rodents or wildlife. Any movable harborage in the immediate vicinity of feed production and feed storage areas that is not necessary to the day-to-day operation of the site must be removed. Harborage that cannot be removed or harborage that is movable but necessary to the day-to-day operation of the site must be checked for signs of rodent or wildlife activity. Rodent bait stations and/or traps must be placed around (and in, if applicable) all feed preparation and storage areas, as well as near any harborage in the vicinity that cannot be removed. The rodent control logbook must document that adequate rodent control procedures have been implemented in the feed production and feed storage areas.

6. Swine must not have access to dead or live wildlife at the site. Dead or live wildlife must not be intentionally fed to swine.

7. Swine at the site must not be fed waste that contains meat.

8. Procedures must be in place and carried out for the prompt removal and proper disposal of dead swine or swine remains found in pens in order to eliminate the opportunity for cannibalism, as well as to prevent the attraction of rodents or wildlife. Such procedures must be documented in the animal disposal plan.

9. General hygiene and sanitation of the site must be maintained at all times to prevent the attraction of rodents and wildlife. Solid non-fecal waste (facility refuse) must be placed in covered receptacles and be regularly removed from the site. Spilled feed also must be regularly removed and properly disposed of.

10. All records required must be kept up to date and readily available for inspection at the site.

In the program, pork production sites are audited by USDA qualified and accredited veterinarians. The purpose of these audits is to observe and collect information about the production site, pig sources, feed sources, feed storage methods, rodent and wildlife control, carcass disposal procedures, and facility hygiene. Information is collected on USDA approved official program audit forms. The USDA regulates the audits to ensure that the program standards are met and certifies that the specified Good Production Practices are in place and are maintained on the audited pork production sites. USDA maintains a database containing program records for each certified site. USDA also maintains oversight of the auditing process by qualifying program auditors and by conducting random spot audits. Spot audits are intended to verify that the program’s Good Production Practices are maintained between scheduled audits and to assure that the audit process is conducted with integrity and in a consistent manner across the program.

In the program, in order for pigs originating from certified sites to be sold into commerce, the swine slaughter facility must have in place a procedure by which pigs from certified sites and edible pork products derived from pigs from certified sites are segregated from pigs and edible pork products originating from non-certified sites. This process is verified by the USDA Food Safety and Inspection Service. Swine slaughter facilities processing pigs from certified sites are responsible for conducting verification testing to confirm the trichinae-free status of those pigs originating from certified production sites. On a regular basis, statistically valid samples of pigs from certified herds are tested at slaughter to verify that on-farm trichinae-infection risk reduction practices are working. This process verification testing is performed using a USDA approved tissue or blood-based post-mortem test, and is regulated by the USDA Agricultural Marketing Service.

Results
In the pilot, 461 production site audits were performed with 450 audits (97.6%) indicating compliance with the good production practices as defined in the program. These sites were granted status in the
program ("enrolled" or "certified"). Random verification testing of 11,713 swine from farms in the pilot certification program resulted in 11,712 negatives and one positive by ELISA. The one positive ELISA result was determined to be a false-positive when a five gram sample of diaphragm was tested negative by artificial digestion.

Discussion

*Trichinella spiralis* is a parasitic nematode affecting animals and people. The disease, trichinellosis, is acquired by consuming encysted larvae of *Trichinella spiralis* in muscle tissue from an infected animal. Consumption of undercooked pork has traditionally been a common source of trichinellosis in humans worldwide. In the U.S., the prevalence of this organism in pork has dropped sharply due to changes in swine management practices within the U.S. pork industry. In 1900, greater than 2.5% of the pigs tested were found to be infected with *Trichinella*. The infection prevalence declined to 0.95% in the 1930's, 0.63% in 1952, 0.16% in 1965, and 0.12% in 1970. The USDA National Animal Health Monitoring System's National Swine Survey in 1995 showed an infection rate of 0.013% (Gamble & Bush 1998).

In the mid 1980s, the convergence of three factors provided a powerful rationale for the development of this program. First, the prevalence of *Trichinella* in U.S. swine reached such a low level that disease free status could be envisioned. Second, there was recognition by U.S. pork industry leaders that international markets were closed to U.S. pork products because of the now inaccurate perception that U.S. produced pork had a comparatively higher risk of being infected with *Trichinella*. Finally, the development of a rapid, ELISA based diagnostic test provided a relatively inexpensive tool for the control program.

The U.S. Trichinae Certification Program is a developing USDA program based on scientific knowledge of the epidemiology of *Trichinella spiralis* and numerous studies demonstrating how specific GPPs can prevent exposure of pigs to this zoonotic parasite. This program is a model program for on-farm assurance of product safety. The International Commission on Trichinellosis in their publication, Recommendations on Methods for the Control of *Trichinella* in Domestic and Wild Animals Intended for Human Consumption, states that, "Modern swine production systems reduce or eliminate risks of swine infection with *Trichinella* and testing of individual animals raised under these conditions could be eliminated." (Gamble et al., 2000). This publication continues with details of the requirements of such production systems. The Trichinae Certification Program meets these standards in all respects.

Conclusion

Uniform standards and federal regulations detailing certification requirements for the program have been developed. The completion of the program pilot, along with the establishment of Federal regulations, represented the final steps in the creation of this national, federally-regulated, certification program.

References


