

response. Each sample tested will be reported as positive or negative, and the official NPIP procedure used to classify the sample must be submitted in addition to the assay response value. A completed worksheet for diagnostic test evaluation is required to be submitted with the compiled output data and may be obtained by contacting the NPIP Senior Coordinator. Data and the completed worksheet for diagnostic test evaluation must be submitted to the NPIP Senior Coordinator 4 months prior to the next scheduled General Conference Committee meeting, which is when approval will be sought.

(5) The findings of the cooperating laboratories will be evaluated by the NPIP Technical Committee, and the Technical Committee will make a majority recommendation whether to approve the test kit to the General Conference Committee at the next scheduled General Conference Committee meeting. If the Technical Committee recommends approval, the final approval will be granted in accordance with the procedures described in §§147.46, 147.47, and 147.48.

(6) Diagnostic test kits that are not licensed by the Service (e.g., bacteriological culturing kits) and that have been approved for use in the NPIP in accordance with this section are listed in the NPIP Program Standards.

(b) *Approved tests modification and removal.* (1) The specific data required for modifications of previously approved tests will be taken on a case-by-case basis by the technical committee.

(2) If the Technical Committee determines that only additional field data is needed at the time of submission for a modification of a previously approved test, allow for a conditional approval for 60 days for data collection side-by-side with a current test. The submitting party must provide complete protocol and study design, including criteria for pass/fail to the Technical Committee. The Technical Committee must review the data prior to final approval. This would only apply to the specific situation where a modified test needs additional field data with poultry to be approved.

(3) Approved diagnostic tests may be removed from the Plan by submission of a proposed change from a partici-

pant, Official State Agency, the Department, or other interested person or industry organization. The data in support of removing an approved test will be compiled and evaluated by the NPIP Technical Committee, and the Technical Committee will make a majority recommendation whether to remove the test kit to the General Conference Committee at the next scheduled General Conference Committee meeting. If the Technical Committee recommends removal, the final decision to remove the test will be granted in accordance with the procedures described in §§147.46, 147.47, and 147.48.

[81 FR 53251, Aug. 12, 2016, as amended at 83 FR 28356, June 19, 2018]

PART 149—VOLUNTARY TRICHINAE CERTIFICATION PROGRAM

Sec.

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AUTHORITY: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136a; 7 CFR 2.22, 2.80, and 371.4.

SOURCE: 73 FR 60479, Oct. 10, 2008, unless otherwise noted.

§ 149.0 Purpose and scope.

The Trichinae Certification Program described in this part is intended to enhance the ability of swine producers, as well as slaughter facilities and other persons that handle or process swine from pork production sites that have been certified under the program, to export fresh pork and pork products to foreign markets.

§ 149.1 Definitions.

Accredited veterinarian. A veterinarian approved by the APHIS Administrator in accordance with part 161 of this chapter to perform functions specified in subchapters B, C, D, and G of this chapter.

Agricultural Marketing Service (AMS). The Agricultural Marketing Service of

the United States Department of Agriculture.

AMS Administrator. The Administrator, Agricultural Marketing Service, or any person authorized to act for the AMS Administrator.

AMS representative. Any individual employed by or acting as an agent on behalf of the Agricultural Marketing Service who is authorized by the AMS Administrator to perform services required by this part.

Animal and Plant Health Inspection Service (APHIS). The Animal and Plant Health Inspection Service of the United States Department of Agriculture.

Animal disposal plan. A written document that describes methods for the removal and disposal of dead swine or swine remains from a pork production site.

Animal movement record. A written record of the movement of swine into or from a pork production site.

APHIS Administrator. The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the APHIS Administrator.

APHIS representative. Any individual employed by or acting as an agent on behalf of the Animal and Plant Health Inspection Service who is authorized by the APHIS Administrator to perform the services required by this part.

Approved laboratory. A non-Federal laboratory approved by the Agricultural Marketing Service and recognized by the APHIS Administrator or FSIS Administrator for performing validated tests to determine the presence of trichinae infection in reference to the Trichinae Certification Program.

Audit. An inspection process, as provided in this part, that generates a written record documenting a pork production site's adherence to the required good production practices.

Auditor. A qualified accredited veterinarian (QAV) or a qualified veterinary medical officer (QVMO) who is trained and authorized by APHIS to perform auditing activities under the Trichinae Certification Program.

Certification (certified). A designation given by the APHIS Administrator to a pork production site for compliance with good production practices and

other program requirements of the Trichinae Certification Program as provided in this part.

Certified pork. Pork products originating from certified swine from a certified production site with identity of such animals or carcasses maintained throughout receiving, handling, and processing.¹

Certified production site. A pork production site that has attained a program status of Stage II or higher, based on adherence to good production practices and other program requirements as provided in this part.

Certified swine. Swine produced under the Trichinae Certification Program on a certified production site.

Confinement unit. A structure on a pork production site in which swine are housed and fed that is totally roofed and that is constructed in such a manner as to prevent swine from being exposed to free-flying birds and other wildlife, and from coming into contact with the carrion of free-flying birds or other wildlife.

Decertification (decertified). Removal of the certified status of a production site by the APHIS Administrator when it has been determined that the criteria of the Trichinae Certification Program are not being met or maintained.

Enzyme-linked immunosorbent assay (ELISA). A method of testing swine for the presence of trichinae infection by looking for antibodies to *Trichinella* spp. in the sera, plasma, whole blood, tissue fluid, or meat juice of swine.

EPA. The United States Environmental Protection Agency.

Feed mill quality assurance affidavit. A written statement signed by the feed mill representative and the producer that documents the quality and safety of feed or feed ingredients delivered from the feed mill to the pork production site.

Food Safety and Inspection Service (FSIS). The Food Safety and Inspection Service of the United States Department of Agriculture.

FSIS Administrator. The Administrator, Food Safety and Inspection

¹The labeling of all certified pork or pork products leaving a slaughter or processing facility must comply with 9 CFR 317.4 and all other applicable FSIS labeling regulations.

Service, or any person authorized to act for the Administrator.

FSIS program employee. Any individual employed by or acting as an agent on behalf of the Food Safety and Inspection Service who is authorized by the FSIS Administrator to perform the services required by this part.

Good manufacturing practices. Feed manufacturing practices that reduce, eliminate, or avoid the risk of exposure of swine to *Trichinella* spp.

Good production practices. Pork production management practices that reduce, eliminate, or avoid the risk of exposure of swine to *Trichinella* spp.

Harborage. Any object, debris, clutter, or area that could serve as shelter or refuge for rodents or wildlife.

Laboratory approval audit. An audit performed by AMS representatives to determine if a laboratory meets minimum requirements for approval, as established by AMS, for performing validated tests under this part.

National Trichinae Certified Herd. All swine raised on certified production sites in the United States.

Person. Any individual, corporation, company, association, firm, partnership, society, joint stock company, or other legal entity.

Pest control operator. A person trained and State-licensed in the control of pests and vermin (particularly rodents).

Pooled sample digestion method (digestion method). A method of testing swine for trichinae infection by identifying the presence of *Trichinella* spp. from a sample of the animal's muscle tissue.

Pork production site (site). A geographically definable area that includes pork production facilities and ancillary structures under common ownership or management systems and the surrounding space within a 100-foot perimeter of the confinement unit.

Positive test result. Outcome of a validated test indicating the presence of *Trichinella* spp.

Premises Identification Number (PIN). A number assigned to a pork production site by the APHIS Administrator.

Process-verification testing. Testing of a statistically valid sample of swine belonging to the National Trichinae Certified Herd at the time of slaughter using a validated test to verify that

the adherence to good manufacturing practices and good production practices is resulting in the absence of *Trichinella* spp. infection in swine from that herd.

Producer. An individual or entity that owns or controls the production or management of swine.

Qualified accredited veterinarian (QAV). An accredited veterinarian who has been granted a program certification by the APHIS Administrator pursuant to §161.5 of this chapter based on completion of an APHIS-approved training program in good production practices in swine management, and who is authorized by the APHIS Administrator to perform site audits and other specified program services required by this part.²

Qualified veterinary medical officer (QVMO). A VMO of the State or Federal Government who is trained in good production practices and is authorized by the APHIS Administrator to perform site audits, spot audits, and other specified program services required by this part.

Rodent control logbook. A written record that documents a rodent control program for a pork production site.

Site audit. An audit, performed by a QAV or a QVMO, to determine the trichinae risk factor status of a pork production site based on the site's adherence to all of the required good production practices that reduce, eliminate, or avoid the risk of exposure of swine to *Trichinella* spp.

Slaughter facility. A slaughtering establishment operating under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) or a State meat inspection act that receives certified swine under the Trichinae Certification Program.

Slaughter facility representative. Any individual employed by, or acting as an agent on behalf of, a slaughter facility who is authorized by the slaughter facility to perform the specified program services required by this part.

² Accredited veterinarians interested in obtaining program certification related to the Trichinae Certification Program should contact APHIS' National Trichinae Coordinator at (515) 284-4122 or write to: USDA, APHIS, Veterinary Services, Trichinae Certification Program, 210 Walnut St., Room 891, Des Moines, IA 50309.

Spot audit. An audit of a certified pork production site performed by a QVMO to ensure program integrity and consistency.

Stage I enrolled. Preliminary program status of a pork production site attained when the APHIS Administrator approves the outcome of an initial site audit.

Stage II certified. Program status attained upon APHIS approval of a site audit of a Stage I enrolled site.

Stage III certified. Program status attained upon APHIS approval of a site audit of a Stage II certified site and maintained upon APHIS approval of subsequent site audits for renewal of Stage III certified status.

Sterile zone. An open area immediately adjacent to and surrounding the confinement unit that serves as both a buffer and detection zone for rodent and wildlife activity.

Temporary withdrawal. The voluntary withdrawal of a certified production site from the Trichinae Certification Program at the request of the producer for a period not to exceed 180 days.

Trichinae. A generic term that refers to *Trichinella* spp.

Trichinae Certification Program (program). A voluntary pre-harvest pork safety program in which APHIS certifies pork production sites that follow all of the required good production practices that reduce, eliminate, or avoid the risk of exposure of swine from their sites to *Trichinella* spp.

Trichinella spp. Parasitic nematodes (roundworms) capable of infecting many warm-blooded carnivores and omnivores, including swine.

USDA. The United States Department of Agriculture.

Validated test. An analytical method licensed by APHIS or accepted by AMS for the diagnosis of *Trichinella* spp. in swine.

Veterinary medical officer (VMO). A veterinarian employed by the State or Federal Government who is authorized to perform official animal health activities on their behalf.

[73 FR 60479, Oct. 10, 2008, as amended at 74 FR 65010, Dec. 9, 2009]

§ 149.2 Program participation.

A producer's initial enrollment and continued participation in the

Trichinae Certification Program requires that the producer adhere to all of the good production practices, as confirmed by periodic site audits, and comply with other recordkeeping and program requirements provided in this part. Pork production sites accepted into the program by APHIS will participate under one of the following three program stages:

(a) *Stage I enrolled status.* (1) Stage I enrolled status signifies that the site has met good production practices and other recordkeeping and program requirements provided in this part.

(2) Swine from a Stage I enrolled site cannot be identified as products from a certified production site.

(3) A Stage I enrolled site must complete a site audit for Stage II certified status in accordance with § 149.3(d). Under § 149.3(d), the site audit must be performed no sooner than 150 days from the date the site was awarded Stage I enrolled status, and must be completed, with the audit form and payment submitted to APHIS, no later than 210 days from the date the site was awarded Stage I enrolled status.

(4) A Stage I enrolled site that is found not to be adhering to one or more good production practices as a result of a site audit or spot audit, or that fails to follow the prescribed timetable for completing a site audit and submitting the completed audit form and payment for consideration as a Stage II certified site, will be subject to a review by APHIS to consider the nature of the infraction(s), and may lose its status as a Stage I enrolled site.

(b) *Stage II certified status.* (1) Stage II certified status signifies that the site is adhering to all of the required good production practices and other recordkeeping and program requirements provided in this part.

(2) An APHIS-issued certificate or letter indicating the site's status as a Stage II certified site must be filed at the site and be readily available for inspection.

(3) Swine from a Stage II certified site may be identified as certified products from a certified production site.

(4) A Stage II certified site must complete a site audit for Stage III certified status in accordance with