

certified status for that shipment of swine.

§ 149.6 Slaughter facilities.

Only slaughter facilities that are under continuous inspection by the Food Safety and Inspection Service or under State inspection that the Food Safety and Inspection Service has recognized as equivalent to Federal inspection may participate in the program. To participate in the program, slaughter facilities must follow the relevant provisions of this section relating to verification, segregation, testing, and recordkeeping. Participating slaughter facilities that fail to comply with any of the applicable requirements of this section will not be allowed to continue to participate in the Trichinae Certification Program and the pork or pork products prepared by the facility will not be eligible for a certificate of export that identifies the product as meeting the standards of the Trichinae Certification Program.

(a) *Verification of certification.* A slaughter facility receiving certified swine must verify the current certification status of the pork production site from which the animals came. The current certification status may be verified by maintaining dated certification documentation on file or by accessing the Trichinae Certification Program Web site on the Internet at <http://www.aphis.usda.gov/vs/trichinae>. If the slaughter facility is unable to verify a site's certification status through documentation on file or through the program Web site, the slaughter facility then should contact the APHIS area office in the State where the site is located.

(b) *Maintaining identity and segregation of certified swine and pork products.* For certified swine to be identified as certified pork, certified swine and edible pork products derived from certified swine must remain segregated from swine and edible pork products from noncertified sites throughout receiving, handling, and processing at the slaughter facility, as well as while awaiting shipment from the facility. The slaughter facility must maintain the identity of the certified swine or pork in a manner that allows the certified swine or pork to be traced back

to the certified production site from which it came. A slaughter facility's failure to properly segregate or maintain the identity of certified swine and edible pork products derived from the certified swine will result in the loss of certified status for that shipment of swine, as well as the edible pork products derived from those animals.

(c) *Process-verification testing.* A slaughter facility processing certified swine is responsible for performing process-verification testing to determine the *Trichinella* spp. infection status of certified swine under its control as follows:

(1) *Validated tests.* Process-verification testing must be performed by using a validated test. When testing involves meat, the sample used for such testing must be at least 20 grams.⁴

(2) *Laboratory approval.* Process-verification testing must be performed in an approved laboratory that has been approved for trichinae testing by the Agricultural Marketing Service (AMS).⁵ The approved laboratory may be maintained and operated by the slaughter facility or by another business entity either on the premises of the slaughter facility or at another location. Laboratory staff performing process-verification testing must be accredited by AMS to perform this program function. For purposes of quality assurance, all laboratory staff approved to perform process-verification testing will receive periodic proficiency test panels from AMS that must be analyzed correctly in order to maintain their approval status.

(3) *Testing sample size and frequency.* Process-verification testing must meet

⁴A copy of the testing methods and checklist for conducting validated tests may be obtained by contacting the AMS Trichinae Analyst and Laboratory Certification Program Manager, USDA, AMS, Science and Technology Programs, Technical Services Branch, 1400 Independence Ave., SW., Mail Stop 0272, Washington, DC 20250-0272. The manager may be contacted by phone at (202) 690-0621.

⁵A copy of the AMS Trichinae Accredited Laboratory Program Requirements may be obtained by contacting the AMS Trichinae Analyst and Laboratory Certification Program Manager (see footnote 4).

the following minimum requirements relating to sample size and frequency:

(i) Slaughter facility representatives shall determine the yearly processing capacity of the slaughter facility for the next 12 months. Officials may use the processing capacity over the previous 12 months if this period is representative of a typical processing year.

(ii) Slaughter facility representatives shall estimate the percentage of swine processed that are likely to come from certified production sites considering all swine expected to be processed at the slaughter facility during the selected 12-month period. Swine that come from certified production sites are considered the eligible population to be sampled.

(iii) Slaughter facility representatives shall use the Trichinae Certification Slaughter Facility Sample Size Determination Table on the Internet at <http://www.aphis.usda.gov/vs/trichinae> to find the number of samples to collect from the population of swine from certified production sites.⁶ If the eligible population is not listed in that table, the next largest number will be used to determine the number of samples to collect. Select the number of samples to collect from the column on that table that reflects a 99 percent confidence level of detecting a positive carcass in a population with a prevalence rate of 0.013 percent. The number selected from the table will be the total number of samples that slaughter facility representatives must collect and test per year and per month during the selected 12-month period.

(iv) For each sample collected, slaughter facility representatives must maintain the identity of the sample using the PIN of the certified production site that was the source of the swine from which the sample was taken.

(v) FSIS program employees at the slaughter facility will review and verify that an adequate number of samples have been collected and that proper frequency of collection is main-

tained. FSIS will report this information to APHIS.

(vi) AMS representatives will verify through a laboratory approval audit that the laboratory performing process-verification testing is correctly following written procedures relating to the receipt, handling, identification, and testing of samples. These written procedures must be maintained by the laboratory in a quality assurance manual, as provided in paragraph (c)(6) of this section. In addition, a laboratory that performs process-verification testing at a location other than the slaughter facility must include a declaration of methodology used to test samples when providing test results.

(vii) The APHIS Administrator may, at APHIS' expense, periodically request that testing be performed on swine brought to the slaughter facility from specific certified production sites. Requests to test swine from specific certified production sites will count towards the slaughter facility's total monthly testing requirement.

(4) *Results of testing.* (i) The results of all process-verification testing relating to certified swine handled at the slaughter facility must be retained in a separate file or notebook as written records at the slaughter facility and must be readily available for inspection by FSIS program employees.

(ii) FSIS will report to APHIS the results of all process-verification testing.

(iii) In the event of a positive test result, the slaughter facility representative must notify the FSIS program employee designated by the FSIS Administrator immediately, who in turn will report the PIN of the certified production site that was the source of the swine from which the sample was taken and the test results of the affected sample to the respective APHIS area office. The following sequence of events must take place following a positive test result:

(A) If a test sample yields a positive test result based on the digestion method, the certified production site that was the source of the swine from which the sample was taken will be de-certified.

(B) If a test sample yields a positive test result based on an ELISA method and is confirmed positive by further

⁶More information regarding sampling sizes may be obtained by writing to USDA, APHIS, Veterinary Services, Trichinae Certification Program, 210 Walnut St., Room 891, Des Moines, IA 50309.

testing using the digestion method, the certified production site that was the source of the swine from which the sample was taken will be decertified.

(C) If a test sample yields a positive test result based on an ELISA method, but is not confirmed positive by further testing using the digestion method, then the certified production site that was the source of the swine from which the sample was taken will be investigated by APHIS.

(1) The investigation may include a spot audit of the affected site. Further testing of animals or carcasses from the affected site also may be performed as part of the investigation. This investigation would determine if the production facility has sufficient safeguards and is following good production practices.

(2) While the affected site is under investigation, its program status as a certified production site will be suspended. While the site is under suspension, the producer must continue to adhere to all of the required good production practices and other recordkeeping and program requirements provided in this part. During this suspension, swine at the site may be sent to slaughter; however, swine from the suspended site cannot be identified as product from a certified production site. The Administrator will determine the program status of the affected site within 30 days of the initiation of the suspension.

(3) A finding that risk factors are inadequately addressed in the site investigation or the finding of additional positive test results based on samples from animals or carcasses from the affected site will be grounds for APHIS decertification of the site.

(5) *Slaughter facility recordkeeping.* (i) All slaughter facilities that receive certified swine must maintain records relating to such animals, including the number of certified swine processed, the source of the certified swine, including the PIN of the certified production site from which the swine came from, and all test results relating to process-verification testing. Records relating to certified swine must be retained at the slaughter facility for a period of at least 3 years following the processing of such animals.

(ii) All slaughter facilities must have documented procedures on how certified swine under its control, and edible pork products derived from certified swine, will remain segregated from swine and edible pork products from noncertified sites throughout receiving, handling, and processing at the facility, as well as while awaiting shipment from the facility. The slaughter facility must also have documented procedures for maintaining the identity of the certified swine or pork with respect to the certified production site from which it came.

(iii) All such records and other documentation required to be maintained by slaughter facilities under this part must be readily available for inspection by FSIS program employees.

(6) *Approved laboratory recordkeeping.* Approved laboratories must have written procedures that specify standards for sample size, sample handling, sample identification, and sample test methods used in process-verification testing. All such written procedures must be maintained in a laboratory quality assurance manual specifically for this program, or as a separate section of an existing laboratory quality assurance manual, and must be retained at the approved laboratory throughout the time the approved laboratory is performing process-verification testing under this program. All such written procedures relating to process-verification testing must be readily available for inspection by FSIS program employees or AMS representatives.

(7) *Slaughter facility overall responsibility for process-verification testing.* The slaughter facility is responsible for obtaining testable samples and for ensuring that the correct number of testable samples are sent to the testing laboratory. Once the slaughtering facility receives the test results, it is responsible for reporting those results in its facility trichinae testing record. Moreover, the slaughter facility is responsible for ensuring that process-verification testing is carried out in accordance with this part, including the reporting of test results, regardless of whether it is performed at the slaughter facility or another location, and regardless of whether the testing is performed by

slaughter facility personnel or other persons.

§ 149.7 Recordkeeping at site.

(a) Stage I enrolled sites, Stage II or Stage III certified sites, and any site that has been suspended or voluntarily decertified must maintain the following program records: Animal disposal plan, animal movement record, feed mill quality assurance affidavit (if applicable), and rodent control logbook. All such records must be readily available for inspection at the pork production site at the time of an audit by a QAV or QVMO, or by other APHIS representatives during normal business hours.

(1) *Animal disposal plan.* The animal disposal plan must meet the following minimum requirements:

(i) It must provide for the removal of all dead swine or swine remains from swine pens immediately upon detection. Inspections for purposes of detecting dead animals must occur at least once every 24 hours.

(ii) It must specify how often and at what intervals the swine pens are observed each day.

(iii) It must provide for the proper storage of dead swine or swine remains in accordance with local, State, and Federal laws and regulations. If the carcass storage facility or composting facility is located on the site, then the animal disposal plan must provide for a storage or composting facility that precludes rodent or wildlife contact with dead swine or swine remains being stored or composted.

(iv) It must provide for the disposal of swine and other mammals by rendering, incineration, composting, burial, or other means, as allowed by and in accordance with local, State, and Federal laws and regulations. For sites that use rendering services, the animal disposal plan also must include the name, address, and phone number of the renderer.

(v) It must be updated as animal disposal practices are changed at the site.

(vi) It must be signed and dated by the producer, as well as the caretaker of the site (if the caretaker is a different person than the producer).

(vii) It may be valid for a period no longer than 2 years after the date of

signature by the producer and (if applicable) the site caretaker.

(2) *Animal movement record.* The animal movement record must meet the following minimum requirements:

(i) It must be filled out completely and properly, accounting for the movement of all non-breeding swine into and from the pork production site.

(ii) In the case of non-breeding swine coming into the site, it must include the date and number of arriving animals, as well as the PIN of the certified production site where the animals originated, or alternatively, if the swine are less than 5 weeks of age and originated from a noncertified site, the name and full address of the noncertified site where the animals originated. The animal movement record must clearly document that all non-breeding swine 5 weeks of age or older arriving at the site originated from another certified production site.

(iii) In the case of non-breeding swine leaving the site, it must include the date and number of departing animals, and their destination.

(iv) It must document the number of dead non-breeding swine that are removed from the site, as well as the number of dead non-breeding swine that are buried or composted at the site, if swine burial or composting is permitted in that State or locality.

(v) All entries to the animal movement record must be signed or initialed and dated by the producer or other site caretaker making the entry.

(3) *Rodent control logbook.* The rodent control logbook, which may include records from a pest control operator, must meet the following minimum requirements:

(i) It must include a rodent control diagram for the site indicating the location of all rodent bait stations and rodent traps at the site. The diagram must be updated whenever bait stations are added, moved, or removed.

(ii) It must document the number of rodent traps set (if applicable), the number of new rodent bait stations set, and how often bait is refreshed.

(iii) It must document the disposal method for all unused bait that is replaced.

(iv) It must document the brand name and active ingredient of bait,