DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 149, 160, and 161

[Docket No. APHIS–2006–0089]

RIN 0579–AB92

Trichinae Certification Program

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations to establish a voluntary Trichinae Certification Program for U.S. pork that has been produced under disease-prevention conditions. Under the program, we will certify pork production sites that follow prescribed good production practices that reduce, eliminate, or avoid the risk of exposure of swine to zoonotic parasites of the genus Trichinella. Such a program should enhance the ability of producers to export pork and pork products to overseas markets. This program has been developed as a cooperative effort by the U.S. Department of Agriculture, the National Pork Board, and the pork processing industry. This program will include those producers who choose to participate in the program, as well as slaughter facilities and other persons that handle or process swine from pork production sites that have been certified under the program.

DATES: *Effective Date:* November 10, 2008.

FOR FURTHER INFORMATION CONTACT: Dr. Dave Pyburn, National Trichinae Coordinator, VS, APHIS, 210 Walnut Street, Room 891, Des Moines, IA 50309; (515) 284–4122.

SUPPLEMENTARY INFORMATION:

Background

Trichinella are parasitic nematodes (roundworms) that are found in many warm-blooded carnivores and omnivores, including swine. There are eight known species of *Trichinella* nematodes: *Trichinella britovi, Trichinella murrelli, Trichinella nativa, Trichinella nelsoni, Trichinella papuae, Trichinella pseudospiralis, Trichinella spiralis,* and *Trichinella zimbabwensis*. Trichinae is a generic term that refers to all species of *Trichinella*.

Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the U.S. Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS) may carry out operations and measures to detect, control, or eradicate any pest or disease of livestock (including the drawing of blood and diagnostic testing of animals). Such operations can include animals at a slaughterhouse, stockyard, or other point of concentration. The Administrator may also cooperate with State authorities, Indian tribal authorities, or other persons in the administration of regulations for the improvement of livestock and livestock products.

Under the Agricultural Marketing Act of 1946 (7 U.S.C. 1622, AMA), the Administrator of APHIS has authority with respect to voluntary inspection and certification of animal products and the inspection, testing, treatment, and certification of animals.

In a proposed rule [1] published in the **Federal Register** on May 16, 2007 (72 FR 27656–27686; Docket No. APHIS–2006–0089), we proposed to establish regulations for a Trichinae Certification Program in 9 CFR part 149. We stated that the Trichinae Certification Program would provide for the certification of pork production sites that follow certain prescribed management practices that reduce, eliminate, or avoid the risk of exposure of swine to *Trichinella* spp. In the proposed rule, we also set forth requirements in the same part for the systematic monitoring and testing of products derived from pigs that originate from certified sites at slaughter facilities, and proposed certain changes to 9 CFR parts 160 and 161 covering the accreditation of veterinarians and veterinary medical officers that are needed for the Trichinae Certification Program.

We solicited comments concerning our proposal for 60 days, ending July 16, 2007. We received comments from five commenters by that date. They were from two organizations representing the U.S. swine industry, one organization representing exporters of U.S. meat products, one organization representing U.S. veterinarians, and a private citizen. They are discussed in the sections below by topic.

General Comments on the Proposed Rule

One commenter stated that the proposed program should be mandatory, rather than voluntary. The commenter suggested that, under a voluntary program, slaughter facilities that do not adhere to production practices and biological security measures that are adequate to preclude the transmission of trichinae from or to swine will not participate, and thus will not be subject to sanitary inspections. The commenter stated that, without mandatory inspections, such sites present a significant risk of spreading trichinae both to the surrounding swine population and to consumers of pork products.

The purpose of the Trichinae Certification Program is to facilitate producers' access to foreign markets by providing them with a means to certify their products as produced under conditions that reduce, eliminate, or avoid the risk of exposure of swine to zoonotic parasites of the genus *Trichinella*. The sanitary measures and site audits stipulated by the proposed rule are necessary for the program to be considered adequate by the foreign markets for which the program is intended. As such, these sanitary measures and audits supplement, but do not replace, existing Food Safety and Inspection Service (FSIS) regulations mandating the inspection of slaughter facilities. These existing regulations include 9 CFR 302.1, which requires most facilities, with limited exemptions, to be inspected by FSIS; 9 CFR 309.1, which mandates ante-mortem inspections of most livestock; and 9 CFR 310.1, which mandates post-mortem inspections of carcasses at slaughter facilities. APHIS regards these existing regulations to be sufficient to mitigate the extremely low risk of pork products infected with trichinae being sold to domestic or foreign consumers.

Another commenter suggested that we combine the provisions of this program with the Agricultural Marketing Service's (AMS') Pork for the European Union (EU) program, which requires producers to engage in process-verification testing.

We are making no changes in response to this comment. The Trichinae Certification Program is intended to facilitate the exportation of fresh pork and pork products to all international markets, not only those within the EU. Because countries outside of the EU sometimes have requirements for process-verification testing and the importation of pork products that differ from those of the EU, combining the two programs might not facilitate the access of domestic producers to those countries' markets.

However, in this final rule, we are making a number of changes to the provisions of the program in order to better align them with the existing standards of the EU. These changes are discussed below in the section entitled ''Comments Regarding the Rule's Consistency with EU Standards.''

[1] To view the proposed rule and the comments we received, go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2006-0089.*

Noting that we used ''trichinae'' throughout the proposed rule as a general term to refer to the nematode *Trichinella spiralis*, one commenter suggested that the term more accurately applies to all species of *Trichinella* nematodes, and we should therefore replace all references to *Trichinella spiralis* with *Trichinella* spp. The commenter suggested that this would not alter the scope of the program, which aims to reduce, eliminate, or avoid the risk of exposure of swine to all *Trichinella* species, not just *Trichinella spiralis*.

We agree with this commenter. We did not include the other species of *Trichinella* in our proposal only because of their current rarity or non-existence in the United States. Accordingly, we are removing all occurrences of the words ''*Trichinella spiralis*'' in the regulatory text and adding ''*Trichinella* spp.'' in their place. The other sections of this final rule also reflect this change.

Finally, one commenter suggested that, once this final rule is published, APHIS should coordinate with the pork and meat-processing industries to draft a program standards document to help producers better understand and participate in the program.

We intend to produce such a document, as well as an auditor's handbook, after the publication of this rule.

Comments Regarding the Rule's Consistency With EU Standards

Several commenters stated that certain provisions of the proposed rule were inconsistent with the standards that the EU has developed for its own trichinae control program. A commenter pointed out that, while the proposed rule's provisions would allow facilities with outdoor swine feeding areas to take part in the program, annex 4(1)(A)(j) of ''Commission Regulation (EEC) No. 2075/2005 of 5 December 2005 laying down specific rules on official controls for *Trichinella* in meat'' forbids certified swine from having any outdoor access.

Another commenter stated that allowing swine that are fed meat-containing food waste to participate in our program would be inconsistent with the standards of other countries. The commenter did not explicitly cite any conflicting international standards. However, only one such standard exists. Articles 22(1)(a–b) of ''European Community Regulation (EEC) No 1774/2002 of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption'' forbid any animal from being fed processed proteins from the bodies of members of its own species and forbid farm animals, other than fur animals, from being fed certain types of meat-containing waste.

Both of these commenters suggested that such discrepancies may impede the EU's recognition of the program, and thus hinder our ability to achieve the stated aim of the proposed rule: 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. Accordingly, the commenters suggested that we forbid outdoor production facilities from participating in the program, remove provisions allowing swine at production facilities to be fed meat-containing waste, and generally reevaluate the proposed rule for consistency with the standards of the EU.

In response to these comments, we have undertaken such a reevaluation. We have determined that the inclusion of outdoor production facilities or facilities with outdoor feeding areas within the program is indeed inconsistent with the standards of the EU, and that such inclusion may impede the ability of the program to facilitate the exportation of fresh pork and pork products to overseas markets. Therefore, we have changed the regulations to exclude such facilities from participating in the Trichinae Certification Program. As a result, in this final rule, only pork production facilities that feed and house pigs in enclosed structures, known as confinement units, may participate in the Trichinae Certification Program. Such confinement units, which are already employed by more than half the pork production sites in the United States, including all of the pork production sites participating in an APHIS-approved trichinae pilot program, and which currently account for the majority of domestic pork production, are constructed in a manner to preclude swine from having outdoor access, to limit the exposure of swine to wildlife and birds, and to limit swine's contact with carrion.

As a result of this change:

- We now include a definition of *confinement unit* in § 149.1 of the regulations. We are defining a *confinement unit* as ''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.'' This definition is generally consistent with the definition of confinement unit that is provided in existing State regulations governing pork production facilities.
- In § 149.1, in the definitions of *pork production site* and *sterile zone*, we have removed references to ''the swine housing and feeding areas'' and ''those buildings used to house or feed swine'' and added ''the confinement unit'' in their place.
- In § 149.3, paragraph (b)(4) now specifies that swine at the site must be housed and fed in a confinement unit. In that same paragraph, we have removed all references to ''swine housing and feeding areas,'' ''buildings housing the swine,'' and ''building(s) used to house and feed swine,'' and have added the words ''confinement unit'' in their place. We have also removed a reference to ''outdoor swine feeding areas.''
- In the same section, paragraph (b)(6) now reads as follows: ''Swine must not have access to dead or live wildlife at the site. Dead or live wildlife must not be intentionally fed to swine.'' In the proposed rule, the paragraph had also prohibited swine from having access to wildlife harborage, including wooded lots and other natural wildlife access areas. That prohibition would have been necessary for outdoor production sites and production sites without confinement units, and thus it is not necessary to include it in this final rule.

We have determined that proposed provisions that would have allowed swine to be fed meat-containing waste products are also inconsistent with EU standards, and may impede the ability of the program to accomplish its stated purpose. Therefore, we have removed the following provisions:

- In § 149.1, the proposed definition *waste feeding logbook* has been removed. Such a logbook is no longer necessary.
- In § 149.3, paragraph (b)(7), which as proposed would have allowed swine to be fed meat-containing waste at a certified production site, now reads as follows: ''Swine at the site must not be fed waste that contains meat.''
- In § 149.7, the introductory text of paragraph (a) no longer refers to a ''waste feeding logbook.'' In the same section, we have removed paragraph (a)(5), which would have established requirements for a waste feeding logbook.

Two commenters stated that, while the proposed rule stipulates that slaughter facility representatives must collect and test enough samples of swine from a certified production site to achieve a 99 percent confidence level of

detecting trichinae if it exists in a certified herd based on a prevalence of 0.013 percent, the EU's trichinae regulations require testing sufficient to achieve a 95 percent confidence level in a sample population. One of these commenters stated that a 99 percent confidence level is therefore unnecessary, and that the confidence level ought to be lowered to 95 percent.

The provisions of this program align with EU standards to the greatest extent possible. However, because the program is voluntary, we expect both the number of swine that could be tested under process-verification testing, and, accordingly, the number that actually will be tested to differ from those of the EU. Thus, adhering to a 99 percent confidence level provides an additional degree of assurance to our trading partners that the standards of the Trichinae Certification Program are sufficiently rigorous, and does not impose a significantly greater amount of process verification testing on a participating slaughter facility than the adoption of a 95 percent confidence level would. If we were to adopt a 95 percent confidence level, a facility that slaughters 5,000 certified swine annually would have to conduct testing on 9 fewer samples yearly than it would in order to achieve a 99 percent confidence level, and a facility that slaughters 1 million certified swine annually would have to test 5,291 fewer samples yearly. In addition, we have determined that process-verification testing under the provisions of the Trichinae Certification Program will cost, at most, approximately $1.72 per swine. Thus, the adoption of a 95 percent confidence level, as opposed to a 99 percent confidence level, would not result in a large difference in the annual cost of process-verification testing for a slaughter facility that participates in the program, relative to the total annual cost of process-verification testing for that facility.

Moreover, by requiring a 99 percent confidence level, we are taking into account the degree of uncertainty that exists regarding the current or future prevalence of trichinae within the U.S. herd. If prevalence rates are, in fact, lower than our estimated 0.013 percent, or some day become lower than 0.013 percent, then the level of testing that we now consider to represent a 99 percent confidence level may, in fact, represent or come to represent a lower confidence level. This is important, because we believe that the maintenance of at least a 95 percent confidence level, regardless of fluctuations in prevalence rates, represents a threshold for our trading partners' recognition of our program. For this reason, we consider the possible benefits derived from maintaining a 99 percent confidence level, as opposed to a 95 percent level, to be greater than the costs associated with attaining that higher confidence level. Therefore, we are making no change to the rule to lower that level.

Finally, as a result of our reevaluation of the provisions of the Trichinae Certification Program in light of EU standards, we have determined that slaughter facilities that conduct process-verification testing involving meat within the Trichinae Certification Program must obtain testing samples of at least 20 grams. The proposed rule did not mandate the size of testing samples.

As a result, in § 149.6, paragraph (c)(1) now reads as follows: ''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.''

Comments Regarding the Scope of the Program

In § 149.0, ''Purpose and scope,'' we state that the purpose of the Trichinae Certification Program is to enhance the ability of domestic 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.

One commenter suggested that we should widen the scope of the program to include the possible use of the program for domestic marketing purposes. Conversely, another commenter expressed concern that the program could result in domestic products being labeled for certification of freedom from trichinae or for compliance with program standards, and suggested that such marketing could have an adverse effect on producers who do not participate in the program.

Although we recognize that producers may wish to participate in the program for domestic marketing purposes, such uses are currently outside the scope of our proposed provisions, as we noted by including a statement about the limited scope and purpose of the program in the regulations. We acknowledge that the Administrator of APHIS has authority under the AMA with respect to voluntary inspection and certification of animal products and the inspection, testing, treatment, and certification of animals. At this time, however, the intent of our rule is to establish a program that will enhance the ability of domestic 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. Any amendments to the scope of the program to include a domestic marketing aspect would be undertaken in a separate rulemaking.

We recognize, moreover, that we referred to the labeling of pork products once in the regulatory text of the proposed rule. In our proposed definition of *certified pork*, footnote 1 stated that the labeling of all pork products leaving a slaughter or processing facility must comply with 9 CFR 317.4 and all other applicable FSIS labeling regulations.

However, we did not intend the footnote as an endorsement of the labeling of pork products destined for domestic or international markets as certified under the Trichinae Certification Program. Rather, we wished to emphasize that the labeling of pork products, whether conducted in conjunction with the Trichinae Certification Program or otherwise, falls under the purview of FSIS, rather than APHIS, and must comply with FSIS regulations. Recognition of such a label as an official label would need to occur through a separate regulatory action.

Comments Regarding Stage I Status

In § 149.2(a) of the proposed rule, we stated that once we initially accept a producer into the certification program, we will award the production site Stage I enrolled status. This stage signifies that a qualified accredited veterinarian (QAV) or qualified veterinary medical officer (QVMO) has performed a site audit of the facility and found it to adhere to the good production practices set forth in § 149.3(b), as well as any additional recordkeeping and program requirements. This stage also signifies that APHIS has received the completed audit form and the program fee of $51 from the producer. A producer awarded Stage I status is acknowledged to be participating in the certification program, but cannot identify swine originating from his or her site as certified products from a certified production site; we are only allowing Stage II and Stage III sites that have passed subsequent site audits to identify their products as certified products from a certified production site. Without such identification, pork products from the site may not undergo process-verification testing at a participating slaughter facility, and a certificate of export identifying the products as being from the Trichinae Certification Program may not be issued.

One commenter suggested that the $51 program fee for producers seeking Stage I status is insufficient, and will ultimately force APHIS to request a larger budget allocation in order to offset the losses generated by the program. Conversely, another commenter pointed out that producers who took part in the pilot programs assumed all costs for obtaining and maintaining compliance with program standards, and would likely be unwilling to pay program fees following implementation of this rule. The commenter stated that, instead of imposing a program fee, APHIS should operate the program out of federally appropriated funds.

In the proposed rule, we itemized and evaluated the pro rata costs associated with the pilot program. These costs included those incurred in providing direct and support labor for the pilot program, estimated agency overhead, and departmental charges. We then divided this number by the total number of applications that had been processed within the pilot program at the time and determined that a $51 program fee, assessed each time a site audit is performed within the Trichinae Certification Program, would be sufficient to cover our administrative costs in processing the audit and operating the program.

However, we do recognize that this fee represents our best estimation of the probable costs associated with processing audit forms and administering the program at the time our evaluation took place, fiscal year (FY) 2005. Therefore, we have reviewed the fee to determine whether it needs to be adjusted for FY 2008 and FY 2009. As a result of this review, and using the same methodology to arrive at the fee as we did in the proposed rule, we have determined that a program fee of $ 51 should cover costs associated with the program in both fiscal years.

We note, moreover, that APHIS regularly reviews all fees that we assess for our programs and, if necessary, undertakes rulemaking to amend them. In accord with this practice, we intend to review the program fee yearly based on the date of the initial implementation of the program, beginning in FY 2010, and will initiate rulemaking each time we need to change it.

Another commenter stated that, by not allowing producers with Stage I enrolled status to identify their swine as certified products or identify their facility as a certified production site, we are limiting the program's ability to immediately facilitate the exportation of fresh pork and pork products to overseas markets. In the commenter's estimation, if the program is operational, but pork products shipped overseas lack identifiable certification of freedom from trichinae, it may take foreign markets several years to formally acknowledge the program. To expedite access to those markets, the commenter suggested that the first sites awarded Stage I status should be considered certified and allowed to immediately begin process-verification testing at participating slaughter facilities.

Section 149.9 of this final rule states that those sites that have been participating in an APHIS-approved trichinae pilot program at the time of implementation of the Trichinae Certification Program will maintain their same program status as Stage I, Stage II, or Stage III certified sites. Thus, pork production sites that obtained certified status within a pilot program will be allowed to immediately identify their swine as certified products from a certified production site within the program. This provision addresses the commenter's concern.

In addition, we regard the provisions of the rule precluding Stage I enrolled sites from immediately identifying their products as certified and engaging in process-verification testing to be necessary for us to determine whether such sites are able to adhere to the good production practices, recordkeeping, and program requirements specified by this rule over a sufficient period of time before obtaining certification. Removing these provisions could impede our ability to adequately assess such adherence, and thus adversely affect the integrity of the program. Specifically, before a site audit takes place for Stage I status within the program, APHIS has no assurance that the site has been adhering to the good production practices of the Trichinae Certification Program up to the point of the audit, and must take into consideration the possibility that swine at the site were produced at one point of their lives under standards at variance with program standards. Under the provisions of the program, any such swine would be sent to slaughter in most circumstances before the site was eligible for Stage II certified status.

Comments Regarding a Change in Ownership of a Certified Production Site

In § 149.2(d) of the proposed rule, we described a protocol for producers to follow in the event that there is a change of ownership in a site participating in the program. If there is a change in ownership to a Stage I enrolled site, the site will continue to operate on the same timetable as under the previous ownership for completing a site audit for Stage II certified status. If there is a change in ownership at a Stage II or Stage III certified site, a site audit must be performed on that site within 60 days of the change of ownership. If the site audit is satisfactory, the site will continue in the program only as a Stage II certified site. A Stage III site that has reverted to a Stage II site because of a change of ownership will be subject to another site audit within 10 months' time; if that audit is satisfactory, we will issue the site a new program anniversary date as a starting date for the purposes of performing future audits. If the results of any site audit arising from a change of ownership are not satisfactory, we may decertify the site, and the site will have to reapply for Stage I enrolled status.

One commenter pointed out that these provisions appear to apply only to a change of ownership of a participating production site. The commenter asked whether a change in ownership of a herd at a production site, without a change in ownership of the site itself, would be subject to a similar protocol.

The provisions are intended to apply to site ownership, not herd ownership. If the ownership of the certified site remains the same, and site audits continue to confirm the facility's adherence to the good production practices stipulated by this rule, the ownership of the swine at the facility may change without triggering the need for the additional audits and other measures described in § 149.2(d).

The same commenter asked which party assumes responsibility for notifying APHIS of this change in ownership of the facility.

The outgoing owner of the facility will notify APHIS of the change in ownership. Once such notification has occurred, the new owner will arrange for a site audit, provided that this new owner wishes to remain within the Trichinae Certification Program. Without such an audit, the site may be subject to decertification, in accordance with § 149.2(e)(1). We have amended § 149.2(d)(2) to reflect this clarification.

Comments Regarding Site Decertification and Renewal

In proposed § 149.2(e)(1), we stated that a Stage II or Stage III certified 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 to continue participation in the program, will be decertified by APHIS. During the time a site is decertified, swine from that site cannot

be identified as certified product from a certified production site. Once a site is decertified by APHIS, a producer wishing to participate in the program again must follow the procedures for requesting a site audit for Stage I enrolled status.

One commenter stated that late payment or an incomplete audit form should not result in decertification of a production site. Instead, the commenter suggested that we should work with producers to address these errors before assessing a penalty, since such errors will usually be clerical in nature.

The same commenter agreed that violations of the good production practices should provide a basis for decertification in certain instances, but stated that we should make a distinction between substantive violations and minor infractions. The commenter suggested that we could differentiate between violations based on whether they can easily be rectified.

We believe decertification would be an appropriate response to substantive violations of good production practices as well as prolonged or repeated failures to observe the program's recordkeeping requirements or timetable for submitting forms and payment.

However, we do recognize that there will be instances of violations that are minor, inadvertent, and easily rectified, and that violations of that nature should not necessarily lead to decertification in all cases. Therefore, we have amended § 149.2(e)(1) to read as follows: ''A Stage II or Stage III certified site that is found not to be adhering to one or more of the good production practices as a result of a site audit, or that fails to follow the prescribed timetable for completing a site audit and submitting the completed audit form and payment to continue participation in the program, will be subject to a review by APHIS to consider the nature of the infraction(s) and to determine whether the site should be decertified. Decertification will result from infraction(s) that APHIS determines to be substantive, prolonged, and/or repeated as a result of this review.''

To reflect this change, we have also amended §§ 149.2, 149.3, and 149.4 to provide that APHIS will conduct a review to consider the nature of possible infractions of the good production practices or administrative requirements associated with the program before decertifying a production site.

We are, however, retaining the provisions in the proposed rule that stated that if a test sample obtained at a slaughter facility from a certified swine yields positive test results based on the pooled digestion method of detecting trichinae, or based on the ELISA method as corroborated by the digestion method, we would decertify the production site that was the source of the swine from which the sample was taken.

Comments Regarding Procedures for a Request for Review

In proposed § 149.2(f), we stated that, if there is a conflict as to any material fact relating to the results of a site audit, spot audit, or other determination affecting the producer's program status or ability to participate in the program, the producer may submit a written request for review to the Administrator. The producer must include in the request the reasons, including any supporting documentation, why the audit result or other determination should be different than the result or determination made by the Administrator. The initial audit result or other determination will remain in force pending the completion of the Administrator's review. The decision by the Administrator upon reviewing the producer's written request will be final.

One commenter pointed out that, under the terms of the proposed rule, APHIS is responsible both for decertifying a site and for evaluating the request for review. The commenter stated that this may present or give the appearance of presenting a conflict of interest, and asked that we amend the rule to have another party evaluate each request for review.

We are making no change in response to this comment. The review process contained in the rule is intended not as a judicial process, but as an opportunity for producers to present information to the Administrator that may help to determine whether the initial decision was in error. Therefore, it is reasonable that APHIS should be responsible both for decertification and review of our determination.

We have used such a process within other certification and approval programs that we administer, and have found it to provide an effective means of review.

Comments Regarding Good Production Practices

In § 149.3(b) of the proposed rule, we set forth good production practices that producers must adhere to in order to participate in the program.

Proposed paragraph (b)(2) stated that all non-breeding swine 5 weeks of age or older that enter a certified site must have originated from another certified production site, and the animal movement record between sites must include the trichinae identification number (TIN) of the certified production site from which the swine originated.

Observing our reference to a TIN, and noting that we defined the TIN as ''a number assigned to a pork production site by the APHIS Administrator,'' two commenters asked whether the premises identification number (PIN) assigned to sites that register their premises for APHIS' National Animal Identification System (NAIS) could take the place of the TIN. The commenters stated that the TIN and PIN appear to serve identical functions, that there is broad support for premises registration within the swine industry, and that the use of an alternate identification system within the certification program may confuse producers who already have a PIN. Accordingly, the commenters suggested that we allow producers who already have a PIN to use this instead of the TIN and that we add a field to our NAIS premises registration forms and our National Premises Identification Repository (NPIR) to allow a producer to identify his or her premises as participating in the Trichinae Certification Program.

On December 19, 2007, APHIS issued the NAIS Business Plan to Advance Animal Disease Traceability (announced at 72 FR 71871–71873).[2] This document recommended strategies and actions that would enable existing State and Federal regulated and voluntary animal health programs, industry-administered management and marketing programs, and various animal identification methods to work in harmony in the NAIS. One of the strategies stated that APHIS will standardize data elements within all APHIS-administered disease programs by using the PIN as the unique location identifier for these programs. Accordingly, each producer who enrolls in the Trichinae Certification Program will be issued a PIN. We have amended the regulatory text in this final rule to reflect this change.

In addition, while the data entry fields in the NPIR are not configured in a way that would allow the association requested by the commenter, we are exploring whether other databases maintained by APHIS' National Center for Animal Health Programs can recognize a producer's certified status within the program and associate it with other data elements. We will provide notice in a future iteration of the program standards if such recognition and association become possible.

Paragraphs (b)(4) and (b)(5) of proposed § 149.3 described measures to be taken to prevent infestations by

[2] The Business Plan is available on the Internet at *http://animalid.aphis.usda.gov/nais/*.

wildlife and rodents, including requirements for the use of rodent bait stations. In both paragraph (b)(4) and (b)(5), we stated that all such rodent bait stations must be intact, systematically maintained, and contain fresh bait that consists of an Environmental Protection Agency (EPA)-registered rodenticide formulation that is applied according to its label.

Noting the requirements for the use of EPA-registered rodenticides as part of the good production practices, one commenter asked whether APHIS had taken into account a notice that EPA published in the **Federal Register** on January 17, 2007 (72 FR 1992–1993; Docket No. EPA–HQ–OPP–2006–0955; FRL–E104–7) that announced the availability of a proposed mitigation decision restricting the use of several rodenticides currently on the market. The commenter asked us to evaluate both the possible increased cost and decreased efficacy of rodenticides as a result of this decision.

On May 28, 2008, EPA released its final decision, titled ''Risk Mitigation Decision for Ten Rodenticides.'' [3] In it, EPA decided not to restrict the use or otherwise alter the efficacy of these rodenticides, but instead decided upon sale and distribution limitations on the products to limit their use in residential settings. EPA's final decision contained an evaluation of the potential economic impacts of these limitations for poultry and livestock producers, and determined that these limitations would not change the availability of the rodenticides for such producers.

Finally, one commenter asked us to consider the use of bird-proofing shields as an additional good production practice. The commenter suggested that the use of such barriers would prevent pigs from exposure to carrion, would add another safeguard to promote rodent control, and would further prevent swine's contact with wildlife.

As noted previously, this final rule provides that only pork production sites that house and feed pigs in confinement units may participate in the Trichinae Certification Program. All confinement units are constructed so as to prevent the exposure of swine to free-flying birds, wildlife, and carrion.

Comments Regarding Renewal of Stage III Certified Status

In § 149.2(c) of the proposed rule, we stipulated that sites that achieve Stage III certified status will be subject to subsequent site audits to determine continued participation in the program. In § 149.3(f), we stated that such site audits must be performed no sooner than 14 months, and no later than 16 months, from either the date the site was awarded Stage III status or the date of the last renewal. If, as a result of any of these renewal audits, we determine that the site is not adhering to one or more of the good production practices, the site will be subject to decertification.

We received two comments regarding these paragraphs. The commenters agreed that the first few renewals should occur at intervals of 14 to 16 months, but stated that subsequent audits for recertification should occur less frequently. One of the commenters stated that the change in frequency should occur after 5 years of successful recertification audits, and that the intervals should increase at that point to no less than 28 months and no more than 32 months. The other commenter suggested that the change should occur after the second successful renewal, and that all subsequent audits should be conducted at a maximum of 30-month intervals. The commenters suggested that making site audits less frequent should reduce the cost of the program and thus facilitate producer participation, yet would not alter it in a manner that could have a negative impact on the domestic perception or international recognition of our standards.

We consider it necessary for at least the first four renewal audits to take place at 14- to 16-month intervals. Such intervals will ensure that, over time, each Stage III site is audited for adherence to the good production practices at least once during each major period for receiving and rendering swine during the calendar year, and, eventually, during each season within the calendar year. This is important, because each season of the year presents producers with unique climatic and environmental conditions, e.g., ground cover during the winter or the increased presence of rodents during the harvest seasons, that can make adherence to the good production practices difficult, and that auditors must be able to assess in determining a producer's ongoing adherence to those practices.

Increasing the time between subsequent audits while the Trichinae Certification Program is still in its initial implementation may adversely impact the program's credibility, and hinder it from accomplishing its stated goal.

However, as the program gains acceptance within the United States and is reviewed by export partners, the intervals between such audits will be reviewed. If we deem longer intervals to be appropriate at that time, we may initiate rulemaking to change them.

Comments Regarding Process-Verification Testing

In proposed § 149.6(c), we stated that slaughter facilities processing certified swine are responsible for performing process-verification testing at their expense in order to determine the *Trichinella* spp. infection status of certified swine under their control. In proposed § 149.6(c)(2), we stated that all testing must be performed in a laboratory that has been approved for trichinae testing by AMS. We further stated that the laboratory may be maintained and operated by the slaughter facility or by another business entity, and may be at the slaughter facility or offsite, but that, regardless of its location, the laboratory staff performing the tests must be approved by AMS, and will be subject to periodic proficiency test panels from AMS that will have to be analyzed correctly in order to maintain approved status.

One commenter asked for clarification regarding the process AMS employs to approve a laboratory, the cost of this initial approval and any subsequent audits/recertification, the possibility of combining such audits and recertification with other programs administered by AMS, the causes of decertification or withdrawal of approval of a laboratory or its personnel, the procedure for recertification, and the ramifications for deviations from standard operating procedures for the laboratory.

Slaughter facilities and other business entities interested in more information regarding the AMS approval process for process-verification testing laboratories should contact the AMS Trichinae Analyst and Laboratory Certification Program Manager. All correspondence should be addressed to 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.

We recognize that this address differs slightly from that provided in footnote 4 of § 149.6 of the proposed rule. We have revised that footnote to reflect this change.

In proposed § 149.6(c)(3)(iii), we stated that, in order to determine the sample size for such testing, the laboratory must use the Trichinae Certification Slaughter Facility Sample Size Determination Table set forth in that paragraph to determine the number

[3] To view this document, go to *http://www.epa.gov/pesticides/reregistration/rodenticides/rodenticides_mitigation_decision.pdf.*

of samples they must collect from the population of swine from certified sites. The table included in the proposed rule set sampling sizes for facilities that expect to process 1,000, 5,000, 25,000, 100,000, 200,000, 400,000, 1 million, 2 million, 4 million, and 5 million certified swine annually, respectively. We stated that the facility must collect the number of samples that reflects a 99 percent confidence level of detecting a positive carcass in a certified herd, based on a disease prevalence of 0.013 percent within that population, and stated that, if the eligible population of swine is not listed in the table, the facility must use the next largest number to determine the number of samples to collect. The number of samples 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 a 12-month period.

A commenter pointed out that, by requiring a facility that expects to process a number of swine not listed on the table to obtain samples from the next largest population, and by providing only 10 population intervals, we will often require facilities to achieve a confidence level of more than 99 percent. If, however, we regard a 99 percent confidence level to be sufficient for the purposes of our program, the commenter proposed that we revise the table to provide population numbers in increments of 1,000 from 1,000 to 10,000, increments of 2,000 from 10,000 to 25,000, increments of 5,000 from 25,000 to 100,000, and increments of 50,000 from 100,000 to 5 million, and that we revise the corresponding yearly and monthly sampling sizes accordingly.

We agree with this commenter, and have therefore revised the table. Because the revised table is large, and because the table does not establish operational procedures but rather clarifies procedures included in § 149.6(c)(3)(iii) for the benefit of participating slaughter facilities, we have removed the table from the regulatory text of the final rule. It will be available on the Internet at *http://www.aphis.usda.gov/vs/trichinae*. We have also added a footnote to § 149.6(c)(3)(iii) stating that more information regarding sampling sizes may be obtained by contacting APHIS' Trichinae Program Manager.

Comment Regarding the Results of Process-Verification Testing

In proposed § 149.6(c)(4), we stated that the results of 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 available for inspection by FSIS program employees.

Proposed paragraph (c)(4)(iii) stated that, in the event of a positive test result, a representative of the slaughter facility must notify an FSIS employee designated by the FSIS Administrator immediately, who in turn will report the TIN 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. We further stated that:

- If a test sample yields a positive test result based on the digestion method of detecting trichinae, then the certified production site that was the source of the swine from which the sample was taken will be decertified.
- If a test sample yields a positive test result based on an ELISA method, and is 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 decertified.
- 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. This investigation may include a spot audit of the affected site, as well as further testing of animals or carcasses from the affected site. The investigation will determine if the site has sufficient safeguards and is following good production practices.

One commenter understood the rule to state that a positive test result will result in audits of the site that was the source of the swine from which the sample was taken, and will cause additional testing to be performed on swine from that site. The commenter requested that APHIS provide more information regarding the nature of this corroborative testing in a future program standards document.

A positive test result from a slaughter facility will result in subsequent testing of other animals from the site that was the source of the swine from which the positive sample was taken only if the sample yields a positive test result under the ELISA method, but does not do so under the digestion method. In such cases, additional testing is necessary to help APHIS to resolve the discrepancy between the two tests. We recognize, however, that we failed to specify the nature of this subsequent testing in the proposed rule. The testing employed will be the ELISA method. We will put such information in the forthcoming program standards document.

In a related matter, however, we recognize that the proposed provisions of this paragraph could be construed to suggest that, while this corroborative testing is ongoing, and while the site is, consequently, suspended from participation in the Trichinae Certification Program, no swine may be sent to slaughter from the site. This is not the case; swine may be sent to slaughter during this time, but not identified as certified products from a certified production site. We have modified the paragraph to reflect this clarification.

Comment Regarding Recordkeeping Requirements

In proposed § 149.7(a), we set forth recordkeeping requirements for producers participating in the program. We stated that all sites would have to maintain the following program records: Animal disposal plan, animal movement record, feed mill quality assurance affidavit (if applicable), and rodent control logbook. As part of the provisions regarding the animal movement record, we stated that producers must document the number of dead non-breeding swine that are removed from the site, as well as the number of non-breeding swine that are buried or composted at the site, if swine burial or composting is permitted in that State or locality.

One commenter stated that information regarding the number of non-breeding swine that are buried or composted at the site constitutes confidential business information, and requested clarification regarding our need to retain such records.

APHIS representatives may need to review this information in order to corroborate the results of an audit. It will be the site owner, not APHIS, who will retain the records.

Comment Regarding QAV Standards

In proposed § 161.5, we set forth requirements for veterinarians who wish to be recognized as qualified accredited veterinarians (QAVs) for the Trichinae Certification Program. We stipulated that, in addition to existing accreditation requirements, such veterinarians need to complete an APHIS-approved orientation or training program regarding the specializations particular to the certification program. Thus, an accredited veterinarian who completes APHIS-approved training in good production practices in swine management could become a QAV and be authorized to perform site audits within the program.

One commenter, upon evaluating the existing accreditation requirements and our new proposed requirement, stated that it appeared that the only prerequisites for obtaining certification as a QAV are the possession of a doctorate in veterinary medicine and successful completion of an APHIS-approved training program. The commenter asked for further clarification regarding the knowledge and experience necessary to obtain certification as a QAV.

QAVs must possess a Doctorate in Veterinary Medicine, must apply for and obtain general accreditation from APHIS under the provisions of 9 CFR part 161, must undergo an APHIS-approved training program in good production practices in swine management, must adhere to the ''Auditor's Handbook'' that we will issue upon implementation of the program, and must seek recertification every two years.

In light of the commenter's question, we recognize that we did not provide a point of contact in our proposal for accredited veterinarians interested in obtaining specializations related to the Trichinae Certification Program. They should contact APHIS' National Trichinae Coordinator, or write to the Trichinae Certification Program office. We are adding contact information for the coordinator and the mailing address for the office to § 149.1, as a footnote to our definition of *qualified accredited veterinarian*.

Miscellaneous Changes

In proposed § 149.2(d)(2), we stated that within 60 days of a change of ownership of a Stage II or Stage III certified site, a site audit must be performed in order for the site to maintain its certified status. We further stated that if the site audit is satisfactory, then the Stage II or Stage III certified site will continue in the program ''only as a Stage II certified site.''

In reviewing our proposal, we have determined that these provisions could be construed as meaning that Stage II or Stage III certified sites that change ownership will be precluded from obtaining Stage III certified status. This is not the case. While a Stage II or Stage III site that changes ownership and obtains a satisfactory site audit will continue in the program initially as a Stage II site, a new program anniversary date for that site will also be established based on the date it was audited. Thus, such sites will be able to request an audit in order to obtain Stage III status 240 days after the site audit resulting from a change of ownership, and must request one no later than 300 days after that audit.

Accordingly, in this final rule, § 149.2(d)(2) states more clearly that a Stage II or Stage III site can continue in the program after a change in ownership initially as a Stage II site following a satisfactory audit, and that a new program anniversary date for that site will be established based on the date the site was audited to continue in the program as a Stage II certified site. The producer of the site will then arrange for a site audit to gain (or regain) Stage III certified status based on that new anniversary date and according to the timetable prescribed in § 149.3(e).

In proposed § 149.2(e)(ii), we stated that, no more than once every two years, a producer may request that one or more certified production sites be temporarily withdrawn from the program. In order to obtain a withdrawal, the producer would have to submit a request in writing to the Administrator.

During the period of withdrawal, swine from the site would not be able to be identified as certified products from a certified production site, but the producer would still have to continue to adhere to all good production practices and other program requirements, unless the Administrator specifically waived a certain requirement in granting the withdrawal.

Before being reinstated, that is, while still under temporary withdrawal status, the site would have to pass a site audit to indicate that it is adhering to all good production practices (including any practices previously waived by the Administrator). If swine 5 weeks of age or older originating from noncertified sources are received at the site during the time of withdrawal, then the site audit for reinstatement must be performed within 30 days of the date the last swine from noncertified sources was removed from the site, but no later than 180 days from the date the site was granted temporary withdrawal status. A site found during the audit not to be adhering to one or more of the good production practices, including any waived during the period of withdrawal, would be subject to decertification.

In reviewing our proposal, we have determined that these provisions appear contradictory, insofar as we require a temporarily withdrawn site to adhere to all the good production practices and program requirements, unless a requirement is explicitly waived by the Administrator, yet seem to allow all temporarily withdrawn sites to receive swine 5 weeks of age or older from noncertified sources, in contravention of one of the good production practices.

We intended these provisions to allow a temporarily withdrawn site to receive swine from a noncertified source, only if the Administrator specifically waived the good production practice prohibiting such reception in granting the producer's request for withdrawal. Therefore, in this final rule, § 149.2(e)(ii) now explicitly states that, in order to maintain status in the program, a temporarily withdrawn production site must obtain a waiver from the Administrator before receiving swine 5 weeks of age or older from a noncertified source.

In proposed § 149.4, we stated that all certified production sites would be subject to spot audits. Spot audits may be performed at random to verify the integrity of the program or, in some cases, to trace back and investigate a positive test result that results from the testing of certified swine from that site at a slaughter facility. In reviewing our proposal, we realize that we failed to state whether a spot audit of a site will affect the timetable that site was following for the completion of subsequent site audits, i.e., whether a new anniversary date will be instituted for the site based on the date that it undergoes the spot audit.

Sites subjected to a spot audit will maintain the same timetable for completion of site audits that they had prior to the spot audit. The reasons for this are twofold, depending on the nature of the spot audit. A site that is the source of certified swine that test positive for trichinae under process-verification testing at a slaughter facility must be considered a potential source of future trichinae infection, even if the site passes a spot audit for cause. It is therefore important that the site maintain the same timetable for completing subsequent audits that it had prior to the spot audit, in order for us to adequately assess the safeguards it has in place and to determine the site's ongoing adherence to the program's good production practices.

A random spot audit does not affect the time table for completion of subsequent audits because the primary aim of such an audit is not to assess a production site for adherence to the good production practices and other program standards, but to ensure the integrity of the auditing process itself by verifying that it is being performed in a consistent manner across the program.

Therefore, paragraph (b) of § 149.4 now specifies that unless a spot audit results in decertification, it does not otherwise affect the timetables for the completion of site audits set forth in this rule.

In proposed § 149.3(a)(5) and proposed § 149.8(a)(1), we stated that, if a QAV performs a site audit, the producer will pay the QAV directly at a mutually agreed-upon time and rate. In reviewing our proposal, we have determined that this provision presupposes that a QAV will charge a producer for the cost of each site audit, and could be construed to specify the nature of the agreement that would occur between the two parties. For these reasons, we have removed this provision from the two paragraphs. Similarly, since a QAV may decide not to charge a producer for the cost of a site audit, we have removed statements in the same proposed paragraphs that a producer is responsible for the cost of the site audit.

Finally, in a related matter, in proposed § 149.3, we twice stated that a producer ''may'' have to contact either a QAV or QVMO in order to conduct a site audit. In proposed paragraph (c)(1), we stated that, when a producer and the producer's herd health personnel believe that a site meets program standards, the producer may arrange for an initial site audit, while, in proposed paragraph (a)(1), we stated that, if a QAV is not available to perform this site audit, the producer may then contact the APHIS area office to request that a QVMO perform the audit.

In reviewing our proposal, we have determined that the use of ''may'' in these two paragraphs could be construed as allowing a producer to forego an initial site audit and yet still become enrolled in the program. This is not the case. We have therefore replaced ''may'' with ''must'' in these two paragraphs.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

In accordance with the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Secretary of Agriculture has the authority to promulgate regulations and conduct programs to detect, control, or eradicate any pest or disease of livestock (including the drawing of blood and diagnostic testing of animals). Such programs can include animals at a slaughterhouse, stockyard, or other point of concentration. The Secretary may also cooperate with State authorities, Indian tribal authorities, or other persons in the administration of regulations for the improvement of livestock and livestock products.

In accordance with 21 U.S.C. 601 *et seq.*, the Secretary of Agriculture is authorized to inspect meat and meat products at any slaughtering, packing, meat-canning, rendering, or similar establishment, while under 21 U.S.C. 451 *et seq.*, the Secretary of Agriculture is authorized to inspect poultry and poultry products at official establishments. Finally, in accordance with 7 U.S.C. 1621 through 1627, the Secretary of Agriculture is authorized to provide a range of voluntary inspection, certification, and identification services to assist in the orderly marketing of various animal products and byproducts.

In this rule, we are establishing regulations for a Trichinae Certification Program. The Trichinae Certification Program provides for the certification of pork production sites that follow certain prescribed management practices that reduce, eliminate, or avoid the risk of exposure of swine to *Trichinella* spp., in order to facilitate producer access to foreign markets. The regulations also set forth requirements for the systematic monitoring and testing of pork products derived from pigs that originate from certified sites at slaughter facilities. Finally, we are making changes to 9 CFR parts 160 and 161 covering the accreditation of veterinarians and veterinary medical officers that are needed for the Trichinae Certification Program.

In accordance with 5 U.S.C. 604, we have prepared a Final Regulatory Flexibility Analysis, which is set out below, regarding the economic impact of this rule on small entities. The discussion also serves as our cost-benefit analysis under Executive Order 12866.

Based upon available data and expected effects, we believe that the benefits of the final rule, in terms of increased exports, may justify the costs of the program for at least some of the participating producers and facilities. It is important to note that program participation will be undertaken on a strictly voluntary basis. Since the program is not mandatory, those producers and slaughter facilities that perceive costs to outweigh potential benefits will opt not to participate in the program.

We first consider potential costs of the rule for participating producers, slaughter facilities, accredited veterinarians, and Federal agencies. We then examine possible benefits of the rule, in terms of increased export market access; we do not consider benefits in terms of reducing the prevalence of trichinae in the domestic herd or in processed pork products because the prevalence rates in both swine and pork products are already extremely low under the status quo. Third, we present alternatives to the rule. Lastly, we address expected impacts for small entities. In that last section, we also summarize and respond to significant issues raised by commenters regarding our initial regulatory flexibility analysis.

Costs for Participating Producers

The number of pork producers in the United States has declined in recent years. According to USDA's National Agricultural Statistics Service (NASS), there were an estimated 76,250 hog and pig producers in the United States in 2002.[4] This was down from 81,220 producers in 2001. Since 2002, the number of producers has declined even further, with 65,540 operations reported in 2006. Although the structure of the industry has changed over time, the number of swine, as well as consumption of pork, has remained relatively constant over the same period.

Participation in this program will be limited to those producers who house and feed swine in confinement units and who do not utilize waste that contains meat in their feeding regimen. Below, we refer to such producers as producers with currently eligible sites. The number of such producers who will participate in the certification program is not known.

Participation by producers with currently eligible sites will depend primarily on economic and other market competitiveness considerations, that is, the expected financial and competitive advantages of participating, or the expected financial and competitive disadvantages of failing to participate. Once the program is implemented, producers with currently eligible sites may find that certain slaughter facilities will be unwilling to purchase swine from pork production sites that are not certified, and that producers who do not participate in the program will therefore face a decline in the marketability or value of their animals. Conversely, they may also find that, by participating in the program, they will be able to earn a premium for their swine at slaughter. Participation by producers with currently eligible sites, therefore, could be driven in large part by the decisions of slaughter facilities. However, the

[4] See NASS *Agricultural Statistics Data Base, http://www.nass.usda.gov/Data_and_Statistics/Quick_Stats/index.asp.*

number of slaughter facilities that will want to use the program in order to certify that their fresh pork and pork products destined for export are produced under the Trichinae Certification Program is also uncertain. In sum, producer participation could be driven largely by slaughter facility participation, and, in turn, slaughter facility participation could be driven by the advantages of certifying pork products exported to foreign markets as having been produced under the Trichinae Certification Program.

Nonetheless, we believe that many producers with currently eligible sites, especially larger ones, are likely to participate in the program. This is because they have already implemented and routinely follow many of the good production practices required for certification, and will likely be able to comply with program standards while incurring minimal costs. Approximately 53 percent of all production sites are classified as total confinement.[5] It is likely that close to 100 percent of commercial pork production sites housing swine in total confinement could meet the program requirements for site certification with, at most, only ''minimal'' facility changes (i.e., those costing approximately $500 over a 5-year period, equivalent to a present value of about $440 when discounted at 7 percent).[6]

In general, larger producers with currently eligible sites are more likely to have many of the risk mitigation measures already in place, and should be more readily able to participate in the program. However, smaller producers with currently eligible sites should also be able to participate in the program at relatively little cost. Since these smaller producers already house swine in confinement units, only ''moderate'' facility changes (i.e., those that cost $2,500 over 5 years) will likely be required.[7] The estimated cost of $2,500 for moderate facility changes consists of $1,500 in first year startup costs and maintenance costs of $250 per year for the next 4 years.[8] Although we anticipate that most producers who decide not to participate in this program will be small in size, other small producers may need to make only minimal or moderate facility changes to satisfy program requirements.

Producers who are currently not producing swine in confinement facilities may participate in the program if they convert to a confinement operation. According to a University of Missouri Extension Service study, a 200-head confinement facility costs approximately $42,000 to construct.[9] This includes costs for water, feeders, site development, and manure storage.

Some of these producers may currently house and feed swine in hoop facilities. Such structures are roofed, but are often exposed at each end, and are typically not constructed in order to preclude swine from exposure to wildlife or rodents. Because of the nature of such structures, these producers may decide that it is more cost-effective to convert their existing facilities into confinement units than to build new confinement units. While no figures exist regarding the cost to convert an existing hoop facility to a confinement unit, a research project conducted by Iowa State University reported the differing levels of investment required for a hoop facility and a confinement facility.[10] According to the study, a confinement facility costs $180 per pig space to build versus $55 per pig space for a hoop facility.

All producers seeking to participate in the program will be required to pay the veterinarians' audit fees for performing both initial and subsequent site audits, assuming the veterinarian decides to assess these fees. APHIS has estimated the fees to be about $150 per audit. After the first three audits are completed, over a 14-to 18-month period and at a possible cost of $450, certified production sites will be subject to audits only once every 14 to 16 months.

In addition to the cost of the site audit, the producer will be responsible for paying a separate program fee to APHIS at the time of each site audit. This program fee will cover APHIS' administrative costs in processing the audit and operating the program. The program fee is $51. Also, producers may have to pay for the postmortem blood, tissue, or meat juice sample tests if the cost of these tests is passed back to them by the slaughter facilities.

For producers who decide to participate in the program, a potential downside is the possibility that swine from their sites could test positive for trichinae at slaughter, resulting in decertification. While a site is decertified, swine from the site may not be identified as product from a certified production site. In order to participate in the program once again, the producer will have to follow the procedures for requesting an initial audit for Stage I enrolled status. We expect that the impact of decertification on a production site will depend upon the extent of the affected producer's reliance on a slaughter facility that participates in the program and that has made a decision regarding purchasing swine from a decertified site that could be disadvantageous to the producer of that site.

Costs for Participating Slaughter Facilities

The number of slaughter facilities that may wish to process certified swine and export their meat as produced under the Trichinae Certification Program is uncertain. As with producers, participation will depend on economic competitiveness considerations. Certain regions (e.g., the EU and the Russian Federation) that import pork require testing for trichinae. Therefore, any facility that wants to export pork to these regions must meet their testing requirements. Slaughter facilities will have to determine whether it will be better to continue to follow their traditional trichinae testing protocols, or whether sourcing animals from certified producers while observing the program requirements for slaughter facilities will provide them an economic incentive.

Slaughter facilities that purchase swine from certified production sites are required to carry out certain functions relating to verification, segregation, testing, and recordkeeping of certified swine under their control. Testing at the slaughter facility entails taking tissue, blood, or meat juice specimens from a sample of the certified swine population processed at the facility in order to determine the *Trichinella* spp. infection status of the tested animals and to verify that the trichinae management practices at the production level are adequate. The number of required test samples will vary among individual facilities, depending on the total number of animals from certified production sites that are slaughtered. The testing requirements are designed to produce a 99 percent confidence level of detecting a positive carcass in the population based on a prevalence of 0.013 percent. For example, a plant that slaughters 1

[5] National Animal Health Monitoring System. October 2007. Part I: Reference of Swine Health and Management Practices in the United States, 2006, National Health Monitoring System. #N475.1007. Fort Collins, CO.

[6] The definition of ''minimal'' expenditures is derived from: Cummings, David and Kopral, Christine, ''Cost Analysis of Trichinae-Free Program Alternatives,'' USDA, APHIS, Centers for Epidemiology and Animal Health, December 1998. This document is referred to below as the CEAH analysis. Copies of the CEAH analysis are available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

[7] For more information on the nature of ''moderate'' expenditures, see the CEAH analysis.

[8] For further information, see the CEAH analysis.

[9] Available online at: *http://extension.missouri.edu/explore/agguides/ansci/g02504.htm.*

[10] Available online at: *http://www.ag.iastate.edu/farms/2001reports/rhodes/AnEconomicAnalysis.pdf.*

million certified swine per year is required to run 34,802 tests annually, but a plant that slaughters 5,000 certified swine per year must run 4,996 tests each year.

Slaughter facilities may conduct sample testing using either an ELISA or a pooled digestion test and have the option of processing the test samples themselves at the slaughter facility or sending the samples to an offsite commercial laboratory. Any laboratory used for such testing must be approved to do so by AMS, and all laboratory staff performing process-verification testing must be accredited by AMS to perform this program function. On-site processing of test samples should result in lower costs per test once the necessary testing equipment is in place. In this regard, it is anticipated that many slaughter facilities, especially the large and medium ones, will acquire or already have acquired ELISA test readers, regardless of whether they participate or intend to participate in the certification program, due to FSIS' hazard analysis and critical control point (HACCP) inspection procedures and because of the public's demand for food safety and quality. ELISA test readers cost about $5,000 each, while pooled diaphragm digestion test readers cost about $2,900.

An ELISA test costs approximately $0.83 per swine using the services of a commercial laboratory, and up to $0.66 per swine if processed by the slaughter facility itself. By comparison, a digestion test costs approximately $1.72 per swine if processed by a commercial laboratory, and $0.92 per swine if processed by the slaughter facility.[11]

An ELISA test, therefore, is less costly than a digestion test. However, if an ELISA test is used and the results are positive, then those findings must be confirmed by using a digestion test. For a large slaughter facility required to run 34,802 tests each year, the ELISA test will cost $28,886 annually if processed by a commercial laboratory and $22,969 if processed by the slaughter facility itself, and the digestion test will cost $59,859 annually if processed by a commercial laboratory and $32,018 if processed by the slaughter facility itself. For a small plant required to run 4,996 tests each year, the ELISA test will cost $4,147 annually offsite and $3,297 annually onsite, and the digestion test will cost $8,593 annually offsite and $4,596 annually onsite.

As discussed above, the number of slaughter facilities that will participate in the program by purchasing swine from certified production sites is uncertain. Slaughter facilities that do accept certified swine and identify pork as produced under the Trichinae Certification Program may pass on some of the testing costs to producers or consumers, depending on price elasticities of supply and demand.

Participating slaughter facilities may experience negative effects from this rule in the event of a trichinae positive test. Given the rarity of trichinae in domestic swine currently, the likelihood of a positive test from an animal that comes from a certified production site is small. However, if there is a positive test result, the slaughter facility will lose the production site from which the infected animal originated as a source of certified swine, due to that site's decertification within the program. On the supply side, then, the cost of a positive test to the slaughter facility will depend on whether it has alternative sources of certified swine available. In addition, a positive test may bring about a decreased demand for the facility's products, depending on buyers' perceptions of the risks associated with purchasing pork products from that facility.

Costs for Participating Accredited Veterinarians

Qualified accredited veterinarians (QAVs) will conduct the site audits for the certification program. We are requiring that the accredited veterinarian be responsible for the cost of periodic training to perform this activity. To become qualified, accredited veterinarians must complete an APHIS-approved training program in good production practices in swine management. At least initially, APHIS' National Trichinae Coordinator will provide this special training to accredited veterinarians, charging an amount sufficient to recover costs. QAVs will need requalification training, but this will not occur more than once every 2 years, and the accredited veterinarians will again be charged a fee to recover costs.

The costs for this special training will be voluntarily incurred by those accredited veterinarians who decide to participate. For the accredited veterinarians who do opt to take the training in order to provide site audits for producers, it will provide a potential source of income in the form of fees received from participating producers for site audits (estimated to be about $150 per audit).

Impact on Federal Agencies

Unlike traditional disease eradication programs, herd certification programs are indefinite, and exist for as long as the producer wishes to maintain certification status. Due to the changes in the meat inspection process that have occurred at the slaughter and processing level, increasingly, packers require various forms of food security certification as criteria for producers who wish to sell their products to them.

With this rule, trichinae certification activities will shift in fiscal year (FY) 2008 from being in a pilot phase to the early national program rollout phase, with implementation of the program in an increasing number of States and involving, potentially, thousands of herds. The program will be made available nationwide to all who volunteer to participate and who meet the eligibility criteria.

Successful implementation of the Trichinae Certification Program will require supporting AMS and FSIS oversight of laboratory and meat-processing facilities. The impacts of the rule on AMS and FSIS operations are expected to be minimal. AMS representatives will certify laboratories with respect to trichinae testing, and FSIS program employees will check records in processing plants to ensure compliance with testing and recordkeeping requirements, as well as provide general oversight that plants are carrying out other program responsibilities properly. The personnel and time requirements for AMS and FSIS to meet their obligations are not expected to be significant. Indeed, AMS has folded expected costs for this program into existing fee structures.

Export Benefits Associated With the Program

The program is designed to facilitate access of domestic pork producers to foreign markets, and may also increase the sales and marketability of fresh pork products destined for those markets. It specifically targets those markets requiring trichinae testing for imported pork products, including the EU and the Russian Federation. Although we expect these markets to acknowledge the Trichinae Certification Program in lieu of the current requirements of testing and freezing, the decision to recognize the certification program has not been made to date, and there is a possibility that these regions will not recognize the program. However, discussions with representatives of the regions are ongoing.

[11] These figures are from the CEAH analysis. It is important to note that, because the CEAH study was published in 1998, the findings are dated. Throughout this analysis, the data used in the CEAH analysis have been updated wherever possible in order to obtain a more current estimate of the cost.

The United States is a net exporter of pork and has been the second largest exporter of pork, trailing the EU, in recent years. Other major exporters include Canada and Brazil. Japan, Mexico, and Canada are the primary markets for U.S. pork exports, accounting for 73 percent of exports. The United States also exports pork to the Russian Federation and the EU, but these exports averaged less than 6 percent of total exports from 2002 to 2005. The year 2006 was marked by an increase in U.S. pork exports to EU and the Russian Federation, to almost 10 percent of total exports.

The Trichinae Certification Program may increase opportunities for participating producers and slaughter facilities to export to regions that monitor for *Trichinella* spp. in pork, but this outcome is uncertain and the extent to which the program may lead to increased exports cannot be determined. U.S. pork exports have been increasing for the past decade, and this trend is expected to continue. On average, 10 percent of U.S. pork production is exported. In 2006, this percentage was notably higher, at 14 percent. Given the steady per capita domestic consumption over the past decade, if U.S. pork production is to continue to grow, the growth likely will be driven by increased export demand. The Trichinae Certification Program may enhance U.S. pork producers' competitiveness in the world market.

According to Canadian animal health personnel, maintaining trichinae-free status for most of Canada has been instrumental in facilitating the country's $1 billion annual export market for pork ($410 million in fresh cuts), as well as in maintaining its annual per capita consumption of pork totaling 28 kg (H. Ray Gamble, Trichinae Fact Sheet, *http://www.aphis.usda.gov/vs/trichinae/*). However, it should be noted that the majority of Canadian exports of pork go to the United States and Mexico, neither of which have trichinae-specific entry requirements for imported pork. So while it may be helpful, it is not certain that the Trichinae Certification Program will automatically lead directly to increased exports of pork and pork products.

As we noted above, the Russian Federation and the EU have traditionally been pork markets where the United States has not had a large presence. It is the industry's hope that the certification program will open these markets more widely to U.S. pork exports. Since 2002, Brazil has been the Russian Federation's largest supplier of pork. However, outbreaks of foot-and-mouth disease in the latter part of 2005 hampered Brazil's supply to that market. Other exporters, including the United States, capitalized on this opportunity to gain market share in the Russian pork market. In addition, in early 2007, the United States signed an agreement with the Russian Federation that allowed pork into the Russian Federation after being either tested for trichinae or frozen. Previously, the Russian Federation had required both testing and freezing. However, since this agreement was signed, Brazil has reentered the Russian market. With the reemergence of Brazil in this market, and their status as the low-cost producer, the United States will have difficulty holding on to any market share gained.

The Trichinae Certification Program may lead to increased exports to regions that require trichinae testing, such as the EU. Historically, the United States has been a net importer of pork from the EU, with exports to the EU remaining steady from 2002 to 2006. In 2007, Bulgaria and Romania joined the EU, and exports to the EU have increased dramatically since their incorporation. However, this increase is driven primarily by trade in lower-value pork products. The U.S. Meat Export Federation (USMEF) believes U.S. exports to the EU will increase further with the certification of new EU-approved plants and the reduction in costs associated with trichinae testing. The current weak dollar will also help the cause of U.S. exports. Increases in exports may not be immediate since there are currently only three EU-approved plants and they are not able to fill the U.S. quota. Furthermore, the USMEF sees a potential for growth in the processed pork products market, i.e., fully cooked bacon, rather than the fresh, chilled, and frozen sector.

Testing costs under the Trichinae Certification Program will outweigh the costs of testing and freezing under the current regime. This is a result of the fact that the United States does not export large amounts of pork to regions having mandatory testing and freezing requirements. In fact, the average costs of testing and freezing per swine slaughtered are $0.02,[12] compared to $0.15 for testing in the lowest cost scenario under the voluntary certification program. This cost comparison assumes the same slaughter numbers in both cases, and a 50 percent participation rate in the Trichinae Certification Program. If only a relatively small amount of pork is exported, the costs of testing under the program will be higher than simply testing each carcass destined for regions with testing and freezing requirements. However, if exports to these regions increase, total testing costs under the Trichinae Certification Program would decline and may eventually become lower than the costs of testing and freezing together, or testing or freezing alone, of every carcass destined for these markets. Thus, benefits in the form of reduced testing costs are dependent upon the level of exports.

[12] Testing costs are derived from the 1998 CEAH study and have been adjusted for inflation. Freezing costs were obtained from Dave Pyburn, the APHIS National Trichinae Coordinator.

Cost-Benefit Summary

As discussed, producers, slaughter facilities, and accredited veterinarians will be subject to certain costs if they choose to participate in the Trichinae Certification Program. Producers may incur added expenses to ensure that their sites meet good production practices. Similarly, slaughter facilities that choose to receive certified swine for processing also may incur additional costs in following program requirements, including the testing of certified swine processed at the facility in order to verify that the good production practices at the production level are adequate and have been followed. Accredited veterinarians who wish to perform site audits will incur the cost of training necessary before performing this service for producers, with benefits accruing in the form of fees received from conducting site audits. The program itself will not impose additional costs on U.S. consumers, although some participating slaughter facilities may pass on a portion of program costs to consumers.

As indicated in the Centers for Epidemiology and Animal Health (CEAH) analysis and described below, a voluntary certification program involving periodic testing at slaughter is less expensive than a program involving mandatory national testing. Also, because the program is voluntary, producers who judge the costs to exceed the benefits for their individual operation may opt not to participate in the program.

Alternatives to the Rule

In considering alternatives to the rule, we looked to the findings of a CEAH analysis of alternatives to the Trichinae Certification Program. The CEAH analysis compared the costs of two alternative methods for achieving Trichinae Certification Program status in U.S. swine: An evolving on-farm certification program (i.e., voluntary program) that involves periodic testing at the slaughter facility versus a national

carcass testing program by the pooled sample digestion method (i.e., mandatory program). Part I of the CEAH analysis describes inputs, assumptions, and projected costs for an evolving on-farm certification alternative. Part II describes inputs, assumptions, and projected costs for a national carcass testing program using the digestion method.

Bottom-line results of this analysis are expressed as the average annual cost per swine over 5 years. It is important to note that, where possible, we have updated the data in the CEAH study through 2002, in order to obtain better estimates of the cost of a voluntary certification program versus a mandatory program. Where recent data are not available, data from the 1998 study were used and adjusted for inflation in years 2 through 5. Although startup and maintenance costs for on-farm certification were averaged over 5 years, actual spending by producers may be higher in the first year and lower in years 2 through 5.

In the CEAH analysis, one component of proposed on-farm certification is periodic ELISA testing at slaughter. Projected costs for on-farm certification were calculated in Part I under options in which (1) large and medium slaughter facilities do required ELISA testing monthly (option (a) in table 1 below) and (2) large and medium slaughter facilities do ELISA testing quarterly (option (b) in table 1 below). It was assumed that small slaughter facilities could only accomplish the required ELISA testing quarterly.

Voluntary Certification Program

In projecting costs for on-farm certification using ELISA testing, the CEAH study found that the most influential variables were the percentage of U.S. producers that would incur no, minimal, or moderate costs to establish and maintain good production practices (GPP) sufficient for on-farm certification, and how much these costs would be. Three GPP scenarios appear in table 1 below. In scenario 1, most producers would incur no additional GPP costs; in scenario 3, conversely, most producers would incur moderate additional costs. Scenario 2 supposes a more or less even distribution among producers who would incur no additional costs, minimal costs, or moderate costs. It was necessary to consider a range of scenarios regarding the percentages of sites that would incur costs, because data, experiences, and perceptions varied significantly. Regarding the dollar amounts of those costs, minimal startup and maintenance costs were estimated to be $500 over 5 years, and moderate costs were estimated to be $2,500 over 5 years.

TABLE 1—AVERAGE ANNUAL COST PER SWINE UNDER ON-FARM CERTIFICATION

Percentage of sites that would incur no additional costs, minimal GPP costs, or moderate GPP costs	Average annual cost per swine over 5 years
(a) Based on monthly ELISA testing at large/medium facilities	
Scenario 1: 90, 5, 5	$0.148
Scenario 2: 36, 32, 32	0.225
Scenario 3: 4, 48, 48	0.271
(b) Based on quarterly ELISA testing at large/medium facilities	
Scenario 1: 90, 5, 5	0.142
Scenario 2: 36, 32, 32	0.219
Scenario 3: 4, 48, 48	0.265

Mandatory Certification Program

The alternative program, national carcass testing by the digestion method as described in Part II of the CEAH analysis, would entail testing every carcass at slaughter. Under this option, USDA would require swine producers to participate in a trichinae certification program. The CEAH analysis assumes that 95 percent of all sites would be certified under a mandatory program. Sites that are not certified would also have to have their swine undergo testing by the digestion method at slaughter. The producers of these non-certified animals would assume the cost of testing.

It is assumed that larger facilities would use their own laboratories for testing, and smaller facilities would send their samples to independent laboratories for testing. All laboratories would be monitored by AMS. Average annual cost per swine under national carcass testing by the digestion method was calculated to be $0.854, which significantly exceeded the highest cost scenario for an on-farm certification program.

Would the additional benefits of a mandatory program outweigh the costs? The CEAH analysis shows that a voluntary certification program involving periodic testing at slaughter is less expensive than a national carcass testing program using the digestion method. While there are no cost estimates for producers who choose not to participate in a voluntary program, it is reasonable to assume that they would choose not to participate based on a cost-benefit calculation, either formal or informal (i.e., expected costs of participating outweigh expected benefits). The CEAH analysis assumes that most of the sites that would not participate in a voluntary program would involve producers with fewer than 100 head of swine. These producers would qualify as small businesses under the Small Business Administration (SBA) criterion, under which producers with not more than $750,000 in annual receipts are considered small businesses. Imposing a mandatory certification program could place an undue burden on swine producers considered to be small businesses.

Maintain Status Quo

Under this option, USDA would not establish a voluntary Trichinae Certification Program. Producers would forgo benefits associated with the program, and any potential benefits from increased exports would not be realized. Producers exporting to regions that monitor for *Trichinella* spp. in pork would continue to test individual animals. The savings that may be realized from a voluntary certification program that would require testing only a sample of animals would not be captured.

Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires agencies to evaluate the potential effects of their proposed and final rules on small business, small organizations, and small governmental jurisdictions. Section 604 of the Act requires agencies to prepare and make available to the public a final regulatory flexibility analysis (FRFA) describing any changes made to the rule as a result of comments received and the steps the agency has taken to minimize any significant economic impacts on small entities. Section 604(a) of the Act specifies the content of a FRFA. In this section, we address these FRFA requirements.

Objectives and Need for the Rule

The objective of the rule is to facilitate producer access to markets that require trichinae testing, specifically the EU and the Russian Federation. The Trichinae Certification Program will be strictly voluntary.

Due to favorable policy changes by the EU regarding the certification of slaughter facilities in the United States, industry participants anticipate that the Trichinae Certification Program may help domestic producers obtain a larger share of the EU market, as well as open that market to the exportation of chilled products. There may be similar effects with respect to the Russian market.

Summary of Significant Issues Raised by Commenters

Comments received covered various aspects of the voluntary program. One commenter expressed concern with the start-up costs for producers wishing to participate in the program that we provided in the proposed rule. The commenter provided revised estimates that the commenter believed better represented these costs. These estimates appeared to suggest that recordkeeping costs would be approximately $750, and stated that the sterile zone that must be maintained surrounding the confinement unit where pigs are housed and fed, as well as the rodent bait stations and/or traps that this zone must contain, would cost an additional $1,523. In total, the commenter estimated that it would cost the average finishing barn $2,659.60 per site, or $2.17 per pig space, to come into compliance with program standards.

APHIS finds the amounts submitted by the commenter to be high, particularly the approximately $750 apparently allocated for recordkeeping. In addition, we have determined that the costs submitted by the commenter for constructing such a sterile zone are also on the high end. In estimating the cost of a sterile zone, the commenter assumed that the regulation requires sterile zones to be constructed of crushed rock. However, we do not require the use of crushed rock for the sterile zone that surrounds the confinement unit. Less expensive level dirt or well-maintained grass may be used in lieu of crushed rock.

With respect to the use of crushed rock in order to construct a sterile zone, we also believe that the commenter overestimated the costs for the construction of such a zone. As a result of correspondence with private companies involved in the construction and maintenance of sterile zones for pork production sites, we have estimated the costs of a sterile zone composed entirely of crushed rock to be between $300 and $600. While we recognize that the commenter's figure of $1,523 also included the cost of the rodent bait stations and/or traps that each sterile zone must contain, we expect that the cost of such rodent control measures will seldom be the bulk of costs associated with the construction and maintenance of a sterile zone.

Another commenter indicated that the EU is moving to align its meat inspection standards more closely with FSIS regulations, which will motivate more U.S. plants to seek EU-approved status. If these regulatory changes are accomplished, additional EU-approved plants will likely lead to increased demand for certified swine and increased participation in the certification program.

Such a scenario is possible, but has not yet occurred, and thus was not considered in this economic analysis.

A commenter stated that, unless packers/exporters will be able to sell an entire certified carcass at a premium by participating in the program, rather than certain certified pork products from that carcass, it is unlikely that most packers/exporters will participate in the program. Moreover, the commenter stated that it is unlikely that most packers/exporters will be able to sell entire carcasses for a premium.

Within the Trichinae Certification Program, the entire carcass of a certified pig and all pork products derived from that carcass are considered certified products, and may be identified as such. The ability of pork packers/exporters to sell the entire certified carcass for a premium will depend on the marketability of U.S. pork products within international markets. The program is designed to facilitate producer access to these overseas markets, rather than to enhance the marketability of pork products within these markets. The decision to export only certain certified pork products to overseas markets, then, rather than entire carcasses, will lie with the packer/exporter, and will depend on market forces outside the scope of this program. However, because of the voluntary nature of the program, those packers/exporters who perceive the costs of program participation to outweigh possible benefits are free to opt not to participate.

One commenter raised the issue of the costs of testing and freezing pork products under the status quo, in comparison with costs of process-verification testing under the Trichinae Certification Program. The commenter stated that testing costs under the program will be lower than those currently paid to test each carcass and freeze the meat from each carcass tested for those foreign markets that require both testing and freezing of imported pork products. However, the commenter pointed out that there are only a few markets that require both testing and freezing of such products. Because of this, the commenter asked whether our analysis had taken into account the costs of process-verification testing as opposed to either testing or freezing, rather than both testing and freezing.

We have determined that testing costs under the voluntary program will initially be higher than the costs of testing or freezing alone, or both testing and freezing together, for those carcasses destined for markets requiring either or both of these trichinae-mitigation measures. However, the reason for this is that the United States currently exports a small amount of pork to regions requiring both testing and freezing. If pork exports to these regions increase, the amount of testing that takes place under the program would commensurately increase, economies of scale would be created, and the cost of testing under the certification program would become more economical than testing or freezing costs under the current regime. We anticipate that such an increase in exports may occur, although we recognize that any increase will be gradual and will require the EU, the Russian Federation, and other regions requiring testing or freezing to accept the certification program.

In the preliminary analysis, we stated that domestic exporters face a duty free quota of 45,000 metric tons (MT) of pork to the EU, and that, in 2005, the United States sent approximately 6,600 MT of pork to the EU. We stated that the National Pork Producers Council (NPPC) had estimated that the implementation of the Trichinae Certification Program would increase exports to the EU by 16,000 MT over those reported in 2005. Finally, we stated that the NPPC had determined that an increase in this magnitude would increase the value of exports by $60 million.

One commenter stated that EU pork tariff rate quotas actually currently allow for 74,600 MT, including 60,500 MT of pork muscle meats, while another commenter stated that the quota of 45,000 MT applies only to bone-in loins and hams. The first commenter added that the import quotas established by the EU directly depend on the amount of pork consumed within the EU, and are intended to limit pork imports to less than 1 percent of total annual consumption. Therefore, it follows that the EU quotas are not set into perpetuity at any fixed amount.

In addition, one commenter stated that a 16,000 MT increase would actually increase the value of exports by $32 million, rather than $60 million.

In response to these comments, we have determined that the number of variables precludes us from estimating the increase in U.S. pork that the EU will import annually as a result of the Trichinae Certification Program, or the value of this increase. We have therefore removed such information from our analysis.

Finally, two commenters submitted the following corrections and clarifications regarding our preliminary analysis:

- Although, on average, approximately 9 percent of U.S. pork production is exported annually, this percentage rose in 2006 to more than 14 percent.
- Although U.S. pork exports to the EU and the Russian Federation did average less than 5 percent of total exports between 2000 and 2005, this percentage rose to almost 10 percent in 2006.
- Whereas we stated that Brazil has historically been the Russian Federation's largest supplier of pork, this status in fact dates back only to 2002. Prior to that time, the EU was the Russian Federation's largest supplier.

We have incorporated this information into our final analysis.

Description and Estimated Number of Small Entities Affected

The final rule will have potential implications for swine producers and slaughter facilities both in terms of the costs they may incur to satisfy program requirements and in terms of the benefits associated with any increase in fresh pork sales as a result of the program's establishment. For both producers and slaughter facilities, the majority of establishments that we expect to take part in the program are small entities (not more than $750,000 in annual receipts for producers and not more than 500 employees for slaughter facilities). Over 80 percent of U.S. swine producers and 95 percent of slaughter facilities are small businesses, according to these SBA guidelines. Because of the voluntary nature of the program, an estimate of the total number of small entities affected by this rule is not possible. However, APHIS personnel associated with the administration of the trichinae pilot programs believe that the majority of producers who took part in those programs were small entities.

In addition to swine producers and slaughter facilities, accredited veterinarians who wish to qualify to conduct site audits will also incur costs associated with obtaining the specialized training necessary for this qualification. Establishments classified as providing veterinary services are likely to be small, although SBA does not provide the level of detail necessary to determine what percentage of these are, in fact, considered small. Only accredited veterinarians who expect to profit from obtaining such specialized accreditation are likely to take part in the Trichinae Certification Program.

Participation of producers in the Trichinae Certification Program will also be voluntary. Small operations may decide not to participate in the program if they believe the costs of attaining and maintaining certified status outweigh the benefits of producing certified swine. As we noted above, these costs may include construction of a confinement unit (approximately $42,000), for those operations that do not currently house and feed swine in total confinement, or ''moderate'' facility changes, (i.e., those that cost $2,500 over 5 years), for those small producers who currently use such units. Slaughter facilities and accredited veterinarians will also face this decision of whether or not to participate. Because participation is voluntary, the final rule is not expected to have an adverse impact on small businesses operating in their own self-interest.

Description and Estimate of Compliance Requirements

Producers are required to pay for site audits by the accredited veterinarian, if the veterinarian charges for this service. Producers are also required to pay program fees for certification by APHIS, and possibly testing. Producers are also required to maintain the following program records: Animal disposal plan, animal movement record, feed mill quality assurance affidavit (if applicable to the producer's operation), and rodent control logbook. Slaughter facilities that purchase swine from certified production sites will be required to carry out certain functions relating to verification, segregation, testing, and recordkeeping of certified swine under their control. Thus, slaughter facilities will be required to keep records of the number of animals slaughtered from certified sites. They will also have to make sure that certified and non-certified animals and products are kept separate throughout processing. Additionally, these facilities will be responsible for keeping records related to testing. In the end, however, it is a voluntary program, so participants will only take on this burden if they feel the program benefits them.

Description of Steps Taken To Minimize Significant Economic Impacts on Small Entities

Since the program is voluntary, we do not expect that the final rule will result in significant economic impacts on small entities.

Summary

This final rule establishes a Trichinae Certification Program. Producers who wish to participate may have to pay for an audit of their production site by a qualified accredited veterinarian. Additionally, they may incur at least a part of the costs of process-verification testing passed on by the slaughter facility conducting the test. However, since this is a purely voluntary program, producers may opt not to incur any of these expenses.

Individuals in the pork industry are hopeful this certification program will help domestic producers gain market share in regions that require trichinae testing, particularly the EU and the Russian Federation. The EU is revising the certification requirements for U.S. slaughter facilities, and industry participants anticipate that the voluntary certification program will substitute for the mandatory testing of all carcasses destined for that market. The benefits of the rule lie in its potential to offer a less expensive alternative to mandatory trichinae testing and increased access to export markets. However, the extent to which foreign markets will become more accessible is unknown.

At present, projected costs under the certification program appear to be higher than current testing costs due to the relatively small amount of product currently exported to the EU and the Russian Federation. However, certain producers may find it to their advantage to participate, given their larger volumes of production and focus on foreign markets.

The program is voluntary and does not impose any direct costs on small or large producers not wishing to participate. If the Trichinae Certification Program expands to include a large percentage of confinement production sites and slaughter facilities, it is possible that non-participating producers could experience a discount in the price or marketability of their swine. In the end, however, producers will participate in the program if they expect the benefits garnered from the certification program will outweigh the costs incurred.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has

no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

National Environmental Policy Act

An environmental assessment and finding of no significant impact have been prepared for this final rule. The environmental assessment provides a basis for the conclusion that the implementation of the Trichinae Certification Program established by this rule will not have a significant impact on the quality of the human environment. Based on the finding of no significant impact, the Administrator of the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

The environmental assessment and finding of no significant impact were prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council of Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

The environmental impact and finding of no significant impact may be viewed on the Regulations.gov Web site.[13] Copies of the environmental assessment and finding of no significant impact are also available for public inspection at USDA, room 1141, South Building, 14th Street and Independence Avenue, SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect copies are requested to call ahead on (202) 690–2817 to facilitate entry into the reading room. In addition, copies may be obtained by writing to the individual listed under **FOR FURTHER INFORMATION CONTACT**.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB) under OMB control number 0579–0323.

[13] Go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2006-0089.* The environmental assessment and finding of no significant impact will appear in the resulting list of documents.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851–2908.

Lists of Subjects

9 CFR Part 149

Animal diseases, Hogs, Laboratories, Meat and meat products, Meat inspection, Reporting and recordkeeping requirements.

9 CFR Part 160

Veterinarians.

9 CFR Part 161

Reporting and recordkeeping requirements, Veterinarians.

■ Accordingly, we are amending 9 CFR chapter I as follows:

Subchapter G—Livestock Improvement

■ 1. In subchapter G, the subchapter heading is revised to read as set forth above.

■ 2. In subchapter G, a new part 149 is added to read as follows:

PART 149—VOLUNTARY TRICHINAE CERTIFICATION PROGRAM

Sec.

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

§ 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 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 an accreditation specialization 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.

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.

[1] The 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.

[2] Accredited veterinarians interested in obtaining specializations 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.

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.

§ 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 § 149.3(e). Under § 149.3(e), the site audit must be performed no sooner than 240 days from the date the site was awarded Stage II certified status, and must be completed, with the audit form and payment submitted to APHIS, no later than 300 days from the date the site was awarded Stage II certified status.

(5) A Stage II certified 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 meet the Stage III site audit requirements of § 149.3(e) within the prescribed timetable, will be subject to a review by APHIS to consider the nature of the infraction(s) and determine whether to decertify the site, as provided in paragraph (e)(1) of this section. During the time a site is decertified, swine from that site cannot be identified as certified products from a certified production site.

(c) *Stage III certified status*.

(1) Stage III 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 III certified site must be filed at the site and be readily available for inspection.

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

(4) In order to maintain Stage III certified status, sites must arrange for site audits to renew such status according to the timetable set forth in § 149.3(f). Under § 149.3(f), the site audit must be performed no sooner than 14 months from the date the site was awarded Stage III certified status or the date that status was last renewed, and must be completed, with the audit form and payment submitted to APHIS, no later than 16 months from either the date the site was awarded Stage III certified status or the date that status was last renewed.

(5) A Stage III certified 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 to determine its continued participation as a Stage III certified site, will be subject to a review by APHIS to consider the nature of the infraction(s) and determine whether to decertify the site, as provided in paragraph (e)(1) of this section. During the time a site is decertified, swine from that site cannot be identified as certified products from a certified production site.

(d) *Change of ownership*—(1) *Stage I enrolled site*. If there is a change in ownership in a Stage I enrolled site, and the new ownership wishes to remain in the program, then the Stage I enrolled site will remain on the same timetable as under the previous ownership for purposes of completing a site audit for Stage II certified status. No additional site audit is necessary as a result of the change of ownership of the site.

(2) *Stage II or Stage III certified sites*. When a change of ownership occurs at a Stage II or Stage III certified site, the previous owner of the site must notify APHIS of this change as soon as the transaction is finalized. Within 60 days of this notification, a site audit must be performed in order for the site to maintain its certified status. It is the new ownership's responsibility that a site audit be performed within 60 days of this notification, otherwise the site may be subject to decertification, in accordance with paragraph (e)(1) of this section. If the site audit is satisfactory, then the Stage II or Stage III certified site will continue in the program, initially as a Stage II certified site. However, a new program anniversary date for that site will be established based on the date the site was audited to continue in the program as a Stage II certified site, and the producer of the site must arrange for a site audit to gain (or regain) Stage III certified status based on that new anniversary date and according to the timetable prescribed in § 149.3(e). If the results of the site audit do not meet program requirements, the Stage II or Stage III site will be subject to a review by APHIS to consider the nature of the infraction(s) and determine whether to decertify the site, as provided in paragraph (e)(1) of this section. Once a site is decertified by APHIS, either because the new ownership fails to arrange for a site audit to be performed within the allotted 60-day time period, or because the site is found not to meet program requirements, a producer wishing to participate in the program again must follow the procedures for requesting an initial audit for Stage I enrolled status. If a decertified site is reenrolled after a successful Stage I site audit, a new program anniversary date for that site will be established based on the date of reenrollment.

(e) *Site decertification and program withdrawal.*

(1) *Decertification by APHIS.*

(i) A Stage II or Stage III certified site that is found not to be adhering to one or more of the good production practices as a result of a site audit, or that fails to follow the prescribed timetable for completing a site audit and submitting the completed audit form and payment to continue participation in the program, will be subject to a review by APHIS to consider the nature of the infraction(s) and to determine whether the site should be decertified. Decertification will result from infraction(s) that APHIS determines to be substantive, prolonged, and/or repeated as a result of this review.

(ii) During the time a site is decertified, swine from such sites cannot be identified as certified products from a certified production site.

(iii) Once a site is decertified by APHIS, a producer wishing to participate in the program again must follow the procedures for requesting a site audit for Stage I enrolled status. If a decertified site is reenrolled after a successful Stage I site audit, a new program anniversary date for that site will be established based on the date of recertification. If a decertified site is recertified after a successful Stage II site audit, a new program anniversary date for that site will be established based on the date of recertification.

(2) *Temporary withdrawal by producer.*

(i) A producer may request that one or more certified production sites be temporarily withdrawn. A producer's request must be made in writing and is subject to the APHIS Administrator's approval.

(ii) Each certified production site can be temporarily withdrawn no more than once every 2 years for a period not to exceed 180 days.

(iii) During the time a site is temporarily withdrawn:

(A) Swine from such sites cannot be identified as certified products from a certified production site; and

(B) The producer must continue to adhere to all good production practices and other recordkeeping and program requirements provided in this part, including documentation in the animal movement record of the arrival and departure of all swine from this site, as well as whether the swine arriving at the site are from certified or noncertified sources, unless a program requirement is specifically waived by the Administrator.

(iv) If granted a waiver by the Administrator, a producer may receive swine 5 weeks of age or older originating from a noncertified source during the period of withdrawal.

(v) Before being reinstated as a certified production site, the temporarily withdrawn site must pass a site audit to indicate that it is now adhering to all good production practices (including any practices waived by the Administrator at the beginning of the period of withdrawal) as follows:

(A) The site audit must be performed while the site is still under temporary withdrawal status. If swine 5 weeks of age or older originating from a noncertified source have been received at the site during the time of withdrawal, then the site audit for reinstatement must be performed within 30 days of the date the last swine from a noncertified source was removed from the site, but no later than 180 days from the date the site was granted temporary withdrawal status.

(B) If the results of the site audit are satisfactory and it is determined that the site is now adhering to good production practices and other program requirements provided in this part, then the withdrawn site will be reinstated as a Stage II certified site. The timetable for performing future site audits for attaining and renewing Stage III certified status will be based on the date the site was reinstated as a Stage II certified site.

(C) If the results of the site audit are not satisfactory, or, if the period of temporary withdrawal has exceeded 180 days, then the site will be subject to a review by APHIS to consider the nature of the infraction(s) and to determine whether to decertify the site, as provided in paragraph (e)(1) of this section. Once the site is decertified by APHIS, the producer must follow the procedures for requesting an initial site audit for Stage I enrolled status in order for the site to be reenrolled in the program. If a site is decertified by APHIS and then reenrolled after a successful Stage I site audit, a new program anniversary date for that site will be established based on the date of enrollment.

(3) *Program withdrawal.*

(i) If a producer decides to withdraw one or more of pork production sites from the program, then it is the producer's responsibility to notify the APHIS Administrator in writing of this intent. When this is done, the site will be removed from the program.

(ii) If at a later date the producer requests that a site be reinstated in the program, then the producer must follow the procedures for requesting an initial audit for Stage I enrolled status. If a withdrawn site is reenrolled after a successful Stage I site audit, then a new program anniversary date for that site will be established based on the date of reenrollment.

(f) *Request for review.* If there is a conflict as to any material fact relating to the results of a site audit, spot audit, or other determination affecting a producer's program status or ability to participate in the program, the producer may submit a written request for review to the Administrator. The producer must include in the request the reasons, including any supporting documentation, why the audit result or other determination should be different than the result or determination made by the Administrator. The initial audit result or other determination will remain in force pending the completion of the Administrator's review. The decision by the Administrator upon reviewing the producer's written request will be final.

§ 149.3 Site audit.

(a) *General.*

(1) The producer must contact a QAV or QVMO to request a site audit. A list of available QAVs may be obtained by accessing the Trichinae Certification Program Web site on the Internet at *http://www.aphis.usda.gov/vs/trichinae*. If a QAV is not available to perform a site audit, the producer must then contact the APHIS area office to request that a QVMO perform the site audit. The site audit is to be arranged at a mutually agreed-upon time.

(2) The producer or the producer's designated representative will accompany the auditor during the site audit.

(3) During the site audit, the auditor will record whether the producer is adhering to all of the required good production practices at the site, as provided in paragraph (b) of this section, in order to reduce, eliminate, or avoid the risk of exposure of swine to *Trichinella* spp.

(4) The auditor will use APHIS-approved audit forms in performing the site audit. After the auditor has completed all sections of the audit form, the producer or the producer's designated representative must sign the audit form attesting to the accuracy of the information obtained during the site audit and to evidence his or her intent to continue adhering to the good production practices and other program requirements, as provided in this part. The auditor also must sign the audit form at this time.

(5) If a QVMO performs the site audit, then the producer will pay the QVMO at the time the site audit is performed

in accordance with the rate and other conditions set by the QVMO's governmental employer. If an APHIS-employed QVMO performs the site audit, then the producer will pay APHIS by certified check or U.S. money order for this service at a rate determined in accordance with § 149.8.

(6) In addition to the possible cost of the site audit, the producer is also responsible for paying a separate program fee in an amount specified in § 149.8 to cover APHIS' administrative costs in processing the audit and operating the program. This program fee, payable to APHIS by certified check or U.S. money order, must be remitted to the auditor at the time each site audit is performed.

(7) The auditor will submit the completed audit form, program fee, and payment for the services of an APHIS-employed QVMO, if applicable, to the nearest APHIS area office. If a QAV performs the site audit, the producer will be responsible for ensuring that the QAV submits the completed audit form and program fee to APHIS in a timely manner.

(8) Upon receipt of the completed audit form and payment, APHIS will determine the initial enrollment or certification status for the site based on an evaluation of the site audit. APHIS will provide the producer with written notification of the audit results. Pork production sites that meet all good production practices as provided in paragraph (b) of this section, as well as other program requirements provided in this part, will be issued program status at the appropriate program stage.

(9) If the site audit shows that the site does not substantively meet all good production practices or other program requirements, APHIS will provide the producer with written notification that includes documentation of the deficiencies that prevented the site from being conferred program status.

(b) *Good production practices.* In a site audit, the auditor will determine whether all of the required good production practices are being carried out at the site to reduce, eliminate, or avoid the risk of exposure of swine to *Trichinella* spp. as follows:

(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, as provided in § 149.7, 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 that 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, as provided in § 149.7.

(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 (evidence of rodent activity consists of fresh rodent droppings, fresh gnawing marks, new structural damage, rodent urine, rodent blood, rodent smear marks (body oil), rodent tracks, or recent burrowing or burrow use. Evidence of wildlife activity consists of wildlife feces, footprints, fur, or hair observed in or near the stored feed or feed ingredients, dead or live wildlife observed in or near the stored feed or feed ingredients, or wildlife burrows or nests observed in or near the stored feed or feed ingredients). 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 (e.g., equipment) 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 (i.e., doorways, vent openings, loading chutes, cool cells, etc.). Interior rodent bait stations and/or traps must be placed near high-risk rodent zones such as entryways, hallways, office areas, swine load-out areas, vents, cool cells, storage areas, utility rooms, cabinets, locker rooms, bathrooms, and break rooms, and systematically maintained. 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 (i.e., residential height grass, flowers, shrubs, or trees). 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, as provided in § 149.7.

(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 (e.g., equipment, etc.) 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 or that is movable but necessary to the day-to-day operation of the site. 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, feed or feed ingredients that are stored in paper bags must be elevated off the floor and be a sufficient distance away from

the walls to allow for inspection, baiting, and/or trapping. The rodent control logbook, as provided in § 149.7, 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, as provided in § 149.7.

(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 under § 149.7 must be kept up to date and readily available for inspection at the site.

(c) *Initial site audit for Stage I enrolled status.*

(1) Producers interested in participating in the program should request and review a pre-audit information packet prepared by APHIS that discusses the program, as well as the steps in preparing for and requesting an initial site audit.[3] When the producer and the producer's herd health personnel believe that a site meets program standards, the producer must arrange for an initial site audit, as provided in paragraph (a) of this section.

(2) Upon completion of the initial site audit and submission of the completed audit form and payment, APHIS will review the completed audit form and make a determination within 30 days as to enrollment of the site in the program. A pork production site that is found to meet all good production practices and other program requirements in this part will be awarded Stage I enrolled status.

[3] The pre-audit information packet may be obtained from a qualified accredited veterinarian (QAV), State or Federal animal health offices, or the National Pork Board, or by writing to: USDA, APHIS, Veterinary Services, Trichinae Certification Program, 210 Walnut St., Room 891, Des Moines, IA 50309. A pre-audit packet also may be requested electronically through the program Web site on the Internet at *http://www.aphis.usda.gov/vs/trichinae.*

(d) *Site audit for Stage II certified status.*

(1) A producer of a Stage I enrolled site must arrange for another site audit for Stage II certified status. The site audit must be performed no sooner than 150 days (i.e., approximately 5 months) 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 (i.e., approximately 7 months) from the date the site was awarded Stage I enrolled status.

(2) APHIS will review the completed audit form and make a determination as to Stage II certified status within 7 days of receipt of the audit form and payment.

(i) A Stage I enrolled site that is found to meet all good production practices and other program requirements in this part will be awarded Stage II certified status.

(ii) A Stage I enrolled site that is found, during a site audit, not to be adhering to one or more good production practices, or that fails to follow the prescribed timetable for completing a site audit and submitting the completed audit form and payment, 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 site.

(e) *Site audit for Stage III certified status.*

(1) A producer of a Stage II enrolled site must arrange for another site audit for Stage III certified status. The site audit must be performed no sooner than 240 days (i.e., approximately 8 months) from the date the site was awarded Stage II certified status, and must be completed, with the audit form and payment submitted to APHIS, no later than 300 days (i.e., approximately 10 months) from the date the site was awarded Stage II certified status.

(2) APHIS will review the completed audit form and make a determination as to Stage III certified status within 30 days of receipt of the audit form and payment.

(i) A Stage II certified site that is found to meet all good production practices and other program requirements in this part will be awarded Stage III certified status.

(ii) A Stage II certified site that is found, during a site audit, not to be adhering to one or more good production practices, or that fails to follow the prescribed timetable for completing a site audit and submitting the completed audit form and payment, will be subject to a review by APHIS to consider the nature of the infraction(s) and determine whether to decertify the site, as provided in § 149.2(e)(1).

(f) *Site audit for renewal of Stage III certified status.*

(1) A producer seeking to renew a site's Stage III certified status must arrange for another site audit. The site audit must be performed no sooner than 14 months from the date the site was awarded Stage III certified status or the date that status was last renewed, and must be completed, with the audit form and payment submitted to APHIS, no later than 16 months from either the date the site was awarded Stage III certified status or the date the that status was last renewed.

(2) APHIS will review the completed audit form and make a determination as to renewing the site's Stage III certified status within 30 days of receipt of the audit form and payment.

(i) A Stage III certified site that is found to meet all good production practices and other program requirements in this part will have its status as a Stage III certified site renewed.

(ii) A Stage III certified site that is found, during a site audit, not to be adhering to one or more good production practices, or that fails to follow the prescribed timetable for completing a site audit and submitting the completed audit form and payment, will be subject to a review by APHIS to consider the nature of the infraction(s) and determine whether to decertify the site, as provided in § 149.2(e)(1).

(Approved by the Office of Management and Budget under control number 0579–0323)

§ 149.4 Spot audit.

(a) In addition to regularly scheduled site audits, certified production sites will be subject to spot audits.

(1) *Random spot audit.* Certified production sites will be selected by the APHIS Administrator at random for a spot audit in order to:

(i) Ensure the integrity of the audit process;

(ii) Verify that the audit process is performed in a consistent manner across the program; and

(iii) Verify that all required good production practices are being maintained between regularly scheduled site audits.

(2) *Spot audit for cause.* A certified production site may be subject to a spot audit to trace back and investigate any positive test results as a result of testing of certified swine from that site at the slaughter facility.

(b) All spot audits will be performed by a QVMO. The producer of the certified production site subject to spot audit will not be charged for the spot audit. APHIS will provide the producer with written notification of the results

of the spot audit, including documentation of any deficiencies noted during the audit. If the site is found not to be adhering to one or more of the required good production practices, then the site will be subject to a review by APHIS to consider the nature of the infraction and to determine whether to decertify the site, as provided in § 149.2(e)(1). Unless a spot audit results in decertification, it does not otherwise affect the timetables for the completion of site audits set forth in paragraphs (e) and (f) of § 149.3.

§ 149.5 Offsite identification and segregation of certified swine.

Certified swine moved from a certified production site to another location, whether to another certified production site, buying station, collection point, or slaughter facility, must remain segregated from noncertified swine at all times and otherwise maintain their identity as certified swine in such a way that they could be readily traced back to the certified production site from which they came. Information relating to the identification of the certified swine must be documented in the animal movement record maintained by the producer. Failure to properly segregate or maintain the identity of certified swine from noncertified swine after leaving the certified production site will result in the loss of 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 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 maintained.

[4] A 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.

[5] A 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).

[6] More 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.

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 decertified.

(B) If a test sample yields a positive test result based on an ELISA method and is confirmed positive by further 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, which must be EPA-registered and applied according to its label, as well as the quantity of bait used (number of pounds).

(v) If possible, it should document the number of rodents caught or killed and indicate how many were rats.

(vi) If possible, it should document the number of rats sighted monthly.

(vii) All entries to the rodent control logbook must be signed or initialed, as well as dated by the producer or other site caretaker making the entry. It must be updated at least monthly.

(4) *Feed mill quality assurance affidavit.* The feed mill quality assurance affidavit, to be used in conjunction with feed or feed ingredients delivered to the pork production site, must meet the following minimum requirements:

(i) It must include the name of the producer and the identity of the site, including the PIN if it has been issued, and the site address, as well as the name and address of the feed mill and the name and title of the feed mill representative.

(ii) It must provide information that the feed mill is following good manufacturing practices, and further specify, as evidence of these good manufacturing practices, the following:

(A) That the feed mill has a rodent control system that is maintained by the feed mill itself or by a pest control firm (include name and address of pest control firm).

(B) The frequency with which such rodent control system is maintained (*i.e.*, on a weekly basis, etc.); and

(C) That the feed mill maintains records of pest management practices or has records generated by a pest control operator, which must be made available to the producer upon request.

(iii) It must be signed by the feed mill representative and by the producer or the producer's designated representative, to remain in effect for a period of 2 years.

(b) All such records and other documentation required under this section must be retained at the pork production site for a period of 2 years.

(c) All such records and other documentation required under this section 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.

(Approved by the Office of Management and Budget under control number 0579–0323)

§ 149.8 Program fees and charges.

(a) *Site audit.* If a QVMO performs the site audit, then the producer will pay the QVMO at the time the site audit is performed in accordance with the rate and other conditions set by the QVMO's governmental employer. Further, if the QVMO who performs the site audit is employed by APHIS, then the producer will pay APHIS for this service at the hourly rate listed in table 1 for each employee required to perform the service. If the APHIS-employed QVMO performs the site audit on a Sunday, on a holiday, or at any time outside the normal tour of duty of that employee, then the producer will pay APHIS for this service at the hourly rate listed in table 2 for each employee required to perform the service. Payment to APHIS for the services of an APHIS-employed QVMO, by certified check or U.S. money order, must be remitted to the QVMO at the time the site audit is performed.

TABLE 1—RATES FOR SERVICES OF QVMO

Hourly rate:	
Per hour	$84.00
Per quarter hour	21.00
Per service minimum fee	25.00

TABLE 2—OVERTIME RATES FOR SERVICES OF QVMO (OUTSIDE THE EMPLOYEE'S NORMAL TOUR OF DUTY)

Premium hourly rate Monday through Saturday and holidays:	
Per hour	$100.00
Per quarter hour	25.00
Premium hourly rate for Sundays:	
Per hour	112.00
Per quarter hour	28.00

(b) *Program fee.* The producer must pay APHIS a program fee at the time of each site audit in the amount of $51 to cover APHIS' administrative costs in processing the audit and operating the program. This program fee, payable to APHIS by certified check or U.S. money order, is due at the time of submitting the completed site audit form for APHIS evaluation.

(c) A producer will not be charged for the cost of having a spot audit performed at the pork production site.

§ 149.9 Pilot program sites.

Pork production sites participating in an APHIS-approved trichinae pilot program at the time of implementation of the Trichinae Certification Program on November 10, 2008 will maintain their same program status as either a Stage I enrolled, Stage II certified, or Stage III certified site, as well as their same program anniversary date for purposes of completing a site audit and submitting the completed audit form and payment.

PART 160—DEFINITION OF TERMS

■ 3. The authority citation for part 160 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 15 U.S.C. 1828; 7 CFR 2.22, 2.80, and 371.4.

■ 4. In § 160.1, a new definition is added, in alphabetical order, for *qualified accredited veterinarian (QAV)* to read as follows:

§ 160.1 Definitions.

* * * * *

Qualified accredited veterinarian (QAV). An accredited veterinarian who has been granted an acccreditation specialization by the Administrator pursuant to § 161.5 of this subchapter based on completion of an APHIS-approved orientation or training program.

* * * * *

PART 161—REQUIREMENTS AND STANDARDS FOR ACCREDITED VETERINARIANS AND SUSPENSION OR REVOCATION OF SUCH ACCREDITATION

■ 5. The authority citation for part 161 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 15 U.S.C. 1828; 7 CFR 2.22, 2.80, and 371.4.

■ 6. Section 161.5 is added to read as follows:

§ 161.5 Specialization.

An accreditation specialization recognized by the Administrator may be granted to an accredited veterinarian upon completion of an orientation or training program approved by APHIS. For certain accredited specializations, the cost of orientation or training may be borne by the accredited veterinarian. An accredited veterinarian granted an accreditation specialization will be referred to as a qualified accredited veterinarian or QAV. A QAV will be authorized to perform those activities and functions specifically provided for elsewhere in this chapter, for example, in part 149.

Done in Washington, DC, this 2nd day of October 2008.

Bruce Knight,

Under Secretary for Marketing and Regulatory Programs.

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