

**SUPPORTING STATEMENT
TRICHINAE CERTIFICATION PROGRAM
OMB NO. 0579-0323**

December 2018

NOTE: This is a reinstatement of a previously approved information collection with changes.

A. Justification

1. Explain the circumstances that make collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

The Animal Health Protection Act (AHPA) of 2002 is the primary Federal law governing the protection of animal health. The law gives the Secretary of Agriculture broad authority to detect, control, or eradicate pests or diseases of livestock or poultry. The Secretary may also prohibit or restrict import or export of any such animal or related material if necessary to prevent spread of any livestock or poultry pest or disease.

The AHPA is contained in Title X, Subtitle E, Sections 10401-18 of P.L. 107-171, May 13, 2002, the Farm Security and Rural Investment Act of 2002.

Trichinella spiralis is a contagious nematode affecting animals and people. The disease, trichinellosis, is transmitted by consuming the meat of an infected animal containing the *Trichinella* cyst. People can get trichinellosis after eating undercooked meat if the meat contains the organism.

Trichinella spiralis was once a zoonotic concern when consuming pork. However, current swine rearing and modern production practices in the U.S. pork industry have greatly reduced the risk for exposing swine to this organism and minimized the likelihood that people will be exposed and infected by eating commercially raised pork. The public expects that on-farm agricultural production methods ensure that the meat provided for consumption is safe.

Swine producers may obtain added value to their swine when their production practices are audited trichinae free. Research and program pilots have shown that it is more practical and efficient to review and audit production methods rather than test individual pork carcasses to certify that the meat is trichinae-safe. Therefore, auditors trained to recognize and record use of trichinae preventing good production practices on-farm will provide information through the official APHIS program audit form for certification purposes. Use of the certification form ensures that swine raised on a pork production site have had minimal exposure or no exposure to the risk factors for *T. spiralis* infection.

Pork industry organizations have worked with USDA and State animal health agencies to develop uniform program standards necessary to reduce and eliminate risk factors associated with Trichinae. These standards provide the national guidelines for implementing the requirements for this program.

APHIS is asking OMB to approve, for 3 years, the use of these information collection activities to certify swine are raised using practices that will reduce or eliminate *T. spiralis* exposure.

2. Indicate how, by whom, how frequently, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

APHIS uses the following information activities to obtain sufficient data to certify swine are raised using practices that will reduce or eliminate *T. spiralis* exposure.

Temporary Withdrawal (Business) - 9 CFR 149.2(e)(2)

A producer may request in writing that one or more certified production sites to be temporarily withdraw from the program. The producer submits this request to APHIS and is subject to the AHIS Administrator's approval. Each certified production site can be temporarily withdrawn no more than once every 2 years for a period not to exceed 180 days.

Program Withdrawal (Business) - 9 CFR 149.2(e)(3)

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.

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.

Request for Review (Business) - 9 CFR 149.2(f)

If the producer questions the results of an audit or other determination affecting the producer's program status, the producer may submit a written request for APHIS review. The request must include the reasons for the review request, any supporting documents, and an explanation why the results or determination should be different. There is no official form for the request.

Request for Certification Site Audit (Business and State) - 9 CFR 149.2(a)

To participate in this program, to receive an enrolled status, and to become certified, pork production sites must call and ask an auditor for an audit of their facilities. The auditor, an accredited veterinarian or State veterinary medical officer who performs other duties on the farm, will already have the contact information (name of producer and phone number) and premises location for the production site and will not need to request that information from the producer.

**Trichinae Certification Site Audit Form (VS 7-9) or Equivalent (Business and State)
9 CFR 149.3**

Auditors (accredited veterinarians or State veterinary medical officers) will visit pork production sites at the owners' request and collect information needed on the Trichinae Certification Site Audit Form. The purpose of the audit is to reduce, eliminate, or avoid the risk of exposing swine to *Trichinella*. As part of the audit, the auditor will observe the swine housing and feeding facilities, review specific on-farm records (such as the animal disposal plan, animal movement records, rodent control logbook, and trichinae herd certification feed mill quality assurance affidavit), and gather responses from the person responsible for care of the swine at the production site regarding good production practices. The auditor will record whether the producer uses all of the required good production practices regarding swine housing, feed, feeding, disposal, animal movement, and general hygiene and sanitation. The owner or caretaker will review and sign the form. The auditor will send the form and payment, if required, to the APHIS Area Office.

Spot Audit (Business and State) – 9 CFR 149.4

APHIS or State auditors can also conduct spot audits of certified sites to confirm the results of regular audits, to verify that good production practices are being maintained between audits, to trace back and investigate positive slaughter verification testing results, and to ensure that audits are conducted consistently across the program. The auditor will record the findings on the Trichinae Certification Site Audit Form. The owner or caretaker will review and sign the form. The auditor will send the form to the APHIS Area Office.

**Animal Disposal Plan and Recordkeeping (VS 7-11) or Equivalent (Business)
9 CFR 149.7 (a)(1)**

The owner or caretaker of the pork production site must complete an animal disposal plan (or similar document). This form should outline the animal disposal practices on the site to include the prompt removal and proper disposal of all dead swine on certified production sites. To be eligible to participate in this program, production sites need to remove all dead swine within 24 hours. This plan is to be updated as animal disposal practices change on the production site or every 2 years. The plan must be signed by the owner or caretaker and retained for 2 years, and be made readily available for the auditor's inspection. The sites do not have to use this form if they have their own records that provide the information the program requires. Review of the form is covered under audit reviews.

**Animal Movement Record and Recordkeeping (VS 7-10) or Equivalent (Business)
9 CFR 149.7 (a)(2)**

The owner or caretaker of the pork production site must complete the animal movement record (or similar document) listing the arrivals and departures of swine to and from the certified production site. This form documents that swine entering the premises originated from other trichinae-certified production sites. Animal movement records should indicate that all pigs greater than 5 weeks of age acquired for feeding purposes originate from a trichinae-certified site. The site producer or caretaker signs these records and retains them for 2 years. These records must be made readily available for the auditor's inspection. The sites do not have to use this form if they have their own records that provide the information the program requires.

**Rodent Control Logbook and Recordkeeping (VS 7-12) or Equivalent (Business)
9 CFR 149.7(a)(3)**

The pork production site must also maintain a rodent control logbook or similar rodent control records. The logbook lists the number of traps set and includes information on the type of bait and an index on caught or killed rodents. A complete logbook must also include a site and facility diagram indicating the location of all rodent bait stations and rodent traps. The site producer or caretaker initials the logbook. The record needs to be filled out at least monthly and retained for 2 years. It must be made readily available for the auditor's inspection. The sites do not have to use the logbook if they have their own records that provide the information the program requires.

**Trichinae Herd Certification Feed Mill Quality Assurance Affidavit and Recordkeeping
(VS 7-13) or Equivalent (Business) - 9 CFR 149.7(a)(4)**

The feed mill quality assurance affidavit is a written statement that documents the quality and safety of feed delivered to the pork production site. It includes the name of the producer and the identity of the site, the name and address of the feed mill, and the name of the feed mill representative. The affidavit must provide information that the feed mill is following good manufacturing practices including rodent control. The producer obtains this information through discussions with the mill manager or quality assurance officer. The producer can use the example affidavit provided with the program standards to the producer to document the information, or keep another document at the production site that

contains the same information. Both the producer and mill representative must sign the affidavit. The affidavit must be retained for 2 years and be made readily available for the auditor's inspection.

Records for Slaughter Testing and Recordkeeping (Business) - 9 CFR 149.6(c)(5)

Slaughter plants participating in this program test a certain percentage of samples each month. Slaughter plant personnel record the location where the sample originated and the test results. The records are maintained in either the slaughter plant or in a laboratory approved for trichinae testing by the Agricultural Marketing Service. 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. The records must be available for APHIS inspection and be retained for 2 years.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

Producers request audits through a phone call, so no form is needed for this request.

All five forms in this information collection, the VS 7-9, 7-10, 7-11, 7-12, and 7-13, are available electronically at www.aphis.usda.gov/vs/trichinae and also at www.aphis.usda.gov/library/forms. Production sites may use other ways to provide the same information. The site audit form is completed during the audit and sent to APHIS after the producer reviews it. The remaining forms are maintained on-farm in hard copy to facilitate the auditing process. Since APHIS does not retain any forms other than the certification audit form, which the producer must sign, electronic submission of the forms is not needed.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purpose described in item 2 above.

The information APHIS collects in connection with this program is not available from any other source. APHIS is the only Agency responsible for certifying that swine are raised according to methods and practices that will reduce or eliminate exposure of the swine to *T. spiralis*.

5. If the collection of information impacts small businesses or other small entities (Item 5 of OMB Form 83-1), describe any methods used to minimize burden.

Approximately 95 percent of the businesses in this information collection are considered small businesses. The information APHIS collects is the minimum needed to determine if swine produced on these sites have had minimal exposure or no exposure to the risk factors for infection with *T. spiralis*. To minimize burden, the farms do not have to use the program forms if they have their own records that provide the information the program requires.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

If this information is collected less frequently or not collected, it will compromise APHIS' ability to monitor activities pertaining to the trichinae certification program and to verify that the producers participating are implementing and completing the trichinae risk mitigation activities.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with the general information collection guidelines in 5 CFR 1320.5

- **requiring respondents to report information to the agency more often than quarterly;**

Rodent Control Log book records need to be filled out at least monthly.

- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;**
- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
- **requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

No other special circumstances exist that would require this collection to be conducted in a manner inconsistent with the general information collection guidelines established in 5 CFR 1320.5.

8. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and record keeping, disclosure, or reporting form (if any), and on the data elements to be recorded, disclosed, or reported. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d) soliciting comments on the information collection prior to submission to OMB.

Participation in this program is decreasing, making it more difficult to identify new, unique contacts. This statement lists one new contact along two we have submitted in the past.

APHIS consulted the following individuals regarding this information collection:

David S. Haworth, DVM
PO Box 320, Okeene, OK 73763
Phone number is 580-822-3713

Dr. Ray Gamble
National Academy of Science
500 Fifth Street, NW
Washington, D.C. 20001
202-334-2787

Dave Pyburn
National Pork Board
1776 NW 114th St
Clive, IA 50325
515-223-2634

On Thursday, February 1, 2018, page 4631, APHIS published in the Federal Register, a 60-day notice seeking public comments on APHIS' plans to request a 3-year extension of this collection of information. During that time, APHIS received no comments.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

This information collection activity involves no payments or gifts to respondents.

10. Describe any assurance of confidentiality to respondents and the basis for the assurance statute, regulation or agency policy.

No additional assurance of confidentiality is provided with this information collection. Any and all information obtained in this collection shall not be disclosed except in accordance with 5 U.S.C.552a.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior or attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

This information collection activity asks no questions of a personal or sensitive nature.

12. Provide estimates of the hour burden of the collection of information.

See APHIS Form 71. Burden estimates were developed from discussions with program participants including auditors, pork producers, mill managers, slaughter facility personnel, and personnel from approved laboratories.

•Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories.

APHIS estimates the total annualized cost to the above respondents to be \$28,272.40. APHIS arrived at this figure by multiplying the total burden hours (520) by the estimated average hourly wage of the respondents ($\$37.14 + 17.23 = 54.37$).

$520 \times \$54.37 = \$28,272.40$

Pork producers: \$12.90 [45-2093 Farm workers, Farm and Ranch Animals]

Auditors: \$56.74 [11-0000 Management Occupations]

Mill managers: \$56.74 [11-0000 Management Occupations]

Slaughter facilities and approved laboratories: \$22.18 [19-4021 Biological Technicians]

The average hourly rate is derived from the current U.S. Department of Labor; Bureau of Labor Statistics Report, May 2017 – National Occupational Employment and Wage Estimates United States. See https://www.bls.gov/oes/current/oes_stru.htm

Benefits = wages X 46.4% ($37.14 \times 0.464 = \$17.37$)

13. Provide an estimate of the total annual cost burden to respondents or record keepers resulting from the collection of information. (Do not include the cost of any hour burden shown in items 12 and 14.) The cost estimate should split into two components: (a) a total capital and startup cost component (annualized over its expected useful life); and (b) a total operation and maintenance and purchase of services component.

No annual cost burden is associated with capital and startup costs, operation and maintenance expenditures, or purchase of services.

However, if a State or Federal veterinarian performs the site audit, then the producer will pay the State or Federal veterinarian at the time the site audit is performed in accordance with the rate and other conditions set by the State or Federal veterinarian's governmental employer. Further, if the State or Federal veterinarian 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 of 9 CFR 149.8 for each employee required to perform the service. If the APHIS-employed veterinarian 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 of 9 CFR 149.8 for each employee required to perform the service. Payment to APHIS for the services of an APHIS-employed veterinarian, by certified check or U.S. money order, must be remitted to the veterinarian at the time the site audit is performed.

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.

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

14. Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost and any other expense that would not have been incurred without this collection of information.

The estimated annualized cost to the Federal Government is \$1,954.29 (see attached APHIS Form 79 for description of estimated cost).

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-L

ICR Summary of Burden:

	Requested	Program Change Due to New Statute	Program Change Due to Agency Discretion	Change Due to Adjustment in Agency Estimate	Change Due to Potential Violation of the PRA	Previously Approved
Annual Number of Responses	1,085	0	1,085	0	0	0
Annual Time Burden (Hr)	521	0	521	0	0	0
Annual Cost Burden (\$)	0	0	0	0	0	0

This is a reinstatement of a previously approved information collection with changes. There is a program increase of +66 respondents and +1,085 responses resulting in an increase of +521 burden hours. APHIS is accounting this as a violation.

16. For collection of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of reports, publication dates and other actions.

APHIS has no plans to publish information it collects in connection with this program.

17. If seeking approval to not display the expiration date for the OMB approval of the information collection, explain the reasons that display would be inappropriate.

Not applicable. APHIS will display the expiration date.

18. Explain each exception to the certification statement identified in “Certification for Paperwork Reduction Act Submissions,” of OMB Form 83-I.

APHIS is able to certify compliance with all the provisions of the Act.

B. Collections of Information Employing Statistical Methods

Statistical methods are not used in this information collection.