

**SUPPORTING STATEMENT - 0579-0323
TRICHINAE CERTIFICATION PROGRAM**

9/25/08

COMMENT: OMB files this comment in accordance with 5 CFR 1320.11(c). This OMB action is not an approval to conduct or sponsor an information collection under the Paperwork Reduction Act of 1995. This action has no effect on any current approvals. If OMB has assigned this ICR a new OMB Control Number, the OMB Control Number will not appear in the active inventory. For future submissions of this information collection, reference the OMB Control Number provided. In accordance with 5 CFR 1320, OMB is not approving the collection at this time. Prior to publication of the final rule, the Agency must submit to OMB a summary of comments received on the information collection burden imposed by the rule and a summary of any changes made to the collection as a result of these comments.

RESPONSE TO COMMENT:

APHIS received 5 comments; however, none of them pertained to paperwork burden.

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.

Title 7, U.S.C. 8301, The Animal Health Protection Act, authorizes the Secretary to prevent, control, and eliminate contagious, infectious, and communicable diseases. Disease prevention is the most effective method of maintaining a healthy animal population, continuing a safe food supply and enhancing APHIS' ability to compete in marketing its animals and animal products worldwide.

Trichinella spiralis is a contagious nematode affecting animals and people. The disease, trichinellosis, is transmitted by consuming the ineffective organism encysted in muscle tissue originating from an infected animal. Consumption of undercooked pork has traditionally been perceived as a common source for exposing people to the organism. Current rearing methods and modern pork production practices implemented today in the U.S. pork industry have greatly reduced the risk for exposing swine to this organism. Therefore, the likelihood that people will be exposed and infected through the consumption of domestic commercial pork has been minimized.

The consuming public expects that agricultural production methods practiced on-farm provide assurances that the meat they consume is safe. It has been determined through research and program pilots that it is more practical and efficient to review and to audit methods of production rather than to test individual pork carcasses to certify that the meat is trichinae-safe. Therefore, auditors trained to recognize and record implementation of trichinae good production practices on-farm will provide information through the official APHIS program audit form to be used for certification purposes. This ensures that swine raised on this pork production site have had minimal exposure or no exposure to the risk factors for infection with *Trichinella spiralis*.

Uniform program standards have been developed by organizations representing the pork industry, State animal health agencies and USDA. These standards provide the national guidelines for implementing the requirements for this program.

APHIS is asking OMB to approve for 3 years this final rule that will include the program audit form and other information gathering and recording tools to obtain sufficient data to certify that swine are raised according to methods and practices which will reduce or eliminate exposure of the swine to *Trichinella spiralis*.

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.

Trichinae Certification Site Audit Form VS 7-9

The information will be collected by USDA, APHIS accredited, trained, and qualified auditors. These auditors will visit pork production sites at the invitation of the site owner. The auditor will observe the swine housing and feeding facilities, review specific on-farm records and gather responses from the person responsible for care of the swine at the production site. The auditor will record these findings on the *Trichinae Certification Form* – the official APHIS audit for the program. The *Trichinae Certification Auditor Handbook* is a supplement to the form. The handbook assists the auditor with gathering this information by providing uniform guidelines and explanations regarding each area and audit item for which this information is sought.

The date of program entry for a certified pork production site will be determined from the date the first audit leading to Stage I enrolled status was completed. All subsequent program dates will be based on this initial date at 6, 9, or 15-month intervals as appropriate. If a site is decertified and must be granted Stage I enrolled status a new anniversary date will be established.

Sites which have the initial audit approved by USDA, APHIS will be granted Stage I status. Stage I enrolled status indicates that the site has met all requirements for the Trichinae Good Production Practices. During Stage I, swine may not be sold as trichinae certified products.

The completed and signed audit form should be sent to the appropriate APHIS Area Office. For new sites, the audit will be reviewed and determination made whether program status is to be

awarded. New sites which meet all Good Production Practice criteria will be issued Stage I status within 30 working days of receipt of the audit form.

Sites with Stage I enrolled status may request an audit for Stage II certified status no sooner than 5 months and must submit a completed audit form no later than 7 months after attaining Stage I enrolled status. If an audit for Stage II certified status is not done within this timeframe then the production site will be removed from the program (decertified).

The completed and signed audit form from a Stage I enrolled site should be sent to the appropriate APHIS Area Office. For Stage I enrolled sites, the audit will be reviewed and the determination made whether Stage II certified status is awarded. Stage I enrolled sites which meet all Good Production Practice criteria will be issued Stage II certified status and trichinae certification within 7 working days of receipt of the audit form. Sites holding Stage II certification may sell swine as originating from a trichinae certified site.

Sites holding Stage II certified status may request an audit for Stage III certified status after 8 months and must submit a completed audit form no later than 10 months following the date of Stage II certified status. If an audit for Stage III certified status is not done within this time-frame then the production site will be removed from the program (decertified).

The completed and signed audit form from a Stage II certified site should be sent to the appropriate APHIS Area Office. For Stage II certified sites, the audit will be reviewed and determination made whether Stage III certified status awarded and certification is continued. Stage II certified sites which meet all Good Production Practice criteria will be issued Stage III certified status and continuation of trichinae certification within 30 working days of receipt of the audit form.

Sites holding Stage III certified status must request a renewal audit no sooner than 14 months and must submit a completed audit form no later than 16 months following the most recent date of certification. If a renewal audit for Stage III certified status is not done within this time frame then the production site will be removed from the program (decertified).

The completed and signed audit form from a Stage III certified site should be sent to the appropriate APHIS Area Office. For Stage III certified sites, the audit will be reviewed and status will be determined. Stage III certified sites which meet all Good Production Practice criteria will be issued Stage III certified status and continuation of certification within 30 working days of receipt of the audit form.

In this program pork producers will be required to fill out the following forms:

The Animal Disposal Plan (VS 7-11) – Retention is for 2 Years

The Animal Disposal Plan (VS 7-11) documents 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 of death and then dispose of them so that they are not an attractant to wildlife or rodents. This plan is to be updated as animal disposal practices change on the production site and/or every 2 years.

The Animal Movement Record (VS 7-10) - Retention is for 2 Years

The Animal Movement Record (VS 7-10) contains documentation of arrivals and departures of swine to and from the certified production site. The example record supplied to the producer with the program information can be used as the required documentation, or another document on file at the production site that contains all relevant animal movement activity information can also be used to document animal movement activities (i.e., Site specific records of animal transfers). Site animal movement records should indicate that all pigs greater than 5 weeks of age acquired by the site for feeding purposes originate from a trichinae certified site. These records should be initialed by the producer and/or caretaker of the production site.

Rodent Control Logbook (VS 7-12) - Retention is for 2 Years

The port production site must also maintain a Rodent Control Logbook (VS 7-12) or similar rodent control records with, at minimum, monthly entries. An example logbook for rodent control in the pork industry has been developed in conjunction with the Trichinae Program. This example is delivered to producers in the program informational materials. A complete logbook must include a site and facility diagram indicating the location of all rodent bait stations and rodent traps. This record needs to be filled out at least monthly.

Trichinae Herd Certification Feed Mill Quality Assurance Affidavit (VS 7-13) - Retention is for 2 Years

The Feed Mill Quality Assurance Affidavit (VS 7-13) is a written statement that documents the quality and safety of feed delivered to the pork production site. The example affidavit supplied to the producer with the program information can be used as the required documentation, or another document on file at the production site that contains all of the same relevant information also can be used to document the safety of the feed being delivered to the site. This affidavit is intended to lead the discussion between the producer and the mill manager or quality assurance officer to ensure the quality and safety of the feed that is being delivered to the pork production site, especially as it relates to trichinae.

Trichinae Record for In-plant Testing - Retention is for 2 Years

In this program swine slaughter facilities will be required to fill out and have on file a record of the results of In-Plant Process Verification Testing that will be done on a monthly basis in each plant participating in the program. These will be retained as written records in the laboratory (if testing is done on site) or in the slaughter facility (if testing is done off-site) and will be available for inspection by the Food Safety Inspection Service (FSIS).

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.

If the site receives certification, the site owner or designated site contact person will receive certification documentation containing the site certification number (TIN – Trichinae Identification Number) and the certification expiration date.

The data entry and certification tracking for this program will be housed in a Generic Database maintained by USDA, APHIS or may be maintained in a compatible database system created and maintained by a participating State Department of Agriculture.

An Internet world wide web page has been developed to maintain a list of certified sites. Listings of certified herds by Trichinae Identification Number (TIN) and program status will be posted on this web page and accessible to program personnel and swine slaughter administrators.

The URL for these forms is www.aphis.usda.gov/vs/trichinae

The burden to the public will be minimized due to maintaining these records in an electronic format.

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 that USDA, APHIS collects is exclusive to its mission of providing leadership in ensuring the health and care of animals and plants, improving agricultural productivity and competitiveness, and contributing to the national economy and the public health.

This is the first time that a form has been created to collect information regarding the methods and production practices used on-farm to produce pork. Previously, programs have tested each pig carcass for presence of *Trichinella spiralis*. The purpose of this alternative method is to collect similar information in a more efficient and practical manner.

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 20% of the respondents in this information collection will be small businesses. The information APHIS will collect 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 *Trichinella spiralis*. The example forms/records provided by the Program can be used for record keeping on the farm and thus provide for a convenient method to ensure the records needed by

this Program are in place on the farm. The example forms/records do not have to be used by the farms as long as they have their own records that provide at the minimum information required by the Program.

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 determine trichinae infection status of pork produced in the U.S.

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

The information collection is conducted in a manner consistent with the 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.

In 2007 APHIS consulted the following individuals to obtain their views regarding this subject:

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Barbara Determan
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APHIS' proposed rule (01-028-1) was published in the Federal Register on Wednesday, May 16, 2007, pages 27656 – 27686. Described its proposed information gathering requirements and also provided a 60-day comment period. During that time, 5 comments were received but they did not pertain to paperwork. The proposed rule is being adopted as the **final** rule, with all changes discussed in the final rule.

9. Explain any decision to provide any payment or gift to respondents, other than reenumeration 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. However, the confidentiality of information is protected under 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.

The burden for the *Trichinae Certification Form* was calculated from data obtained during a pilot study. Approximately one hour will be needed to complete the form. APHIS estimated a value of \$30.00 per hour for the producer's time. Sites just entering into the Program and going through the first stages of the Program will need to have 3 audits performed within a 15 month time span. After this the renewal of site certification requires that site audits be performed once every 15 months. If ownership of a certified site changes they are required to go through 2 audits in a 9 month time span before they are returned to the 15 month renewal cycle. Furthermore, 5% of these sites will be spot audited each year. The associated cost of producers'

time associated with the collection of this information is estimated to be \$1,754,160, annually (see APHIS Form 71).

\$30.00 is the hourly rate derived from the U.S. Department of Labor, Bureau of Labor Statistics May 2006 Report - National Compensation Survey: Occupational Wages in the United States, May 2006. See http://www.bls.gov/oes/current/oes_nat.htm

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.

There is zero annual cost burden associated with capital and start-up costs, operation and maintenance expenditures, and purchase of services.

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.

Administrative and overhead costs for this certification program is estimated to cost \$79,431 (see APHIS Form 79).

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

This is a new collection to obtain sufficient data to certify that swine are raised according to methods and practices which will reduce or eliminate exposure of the swine to *Trichinella Spiralis*. The burden hours have decreased by 4,190 hours due to a calculation error in the proposed rule. Also, VS Form 7-14, Waste Feeding Logbook, has been deleted because swine will not be fed meat-containing waste products.

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.

No publication of collected information is planned. Summaries and a list of participants that have been certified will be available to program personnel.

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.

If the forms were to be discarded due to an outdated OMB expiration date, but otherwise useable, higher printing costs would be incurred by the Federal government. Therefore, APHIS is seeking approval not to display the OMB expiration date on its forms.

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.