

Supporting Statement
Export Certification: Accreditation of
Non-Government Facilities
OMB 0579-0130

A. JUSTIFICATION

April 2014

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection.

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), is responsible for preventing plant diseases or insect pests from entering the United States, preventing the spread of pests and noxious weeds not widely distributed in the United States, and eradicating those imported pests when eradication is feasible. The Plant Protection Act authorizes the Department to carry out this mission.

In addition to its mission, APHIS also provides export certification services to ensure other countries that the plants and plant products they are receiving from the United States are free of plant diseases and insect pests.

The export certification regulations contained in Title 7 of the Code of Federal Regulations (CFR), Part 353 describe the procedures for obtaining certification for plants and plant products offered for export or re-export.

It should be noted that APHIS' regulations do not require that APHIS engage in export certification activities; however, APHIS performs this work as a service to exporters who are shipping plants or plant products to countries that require phytosanitary certification as a condition of entry.

Currently, only tests conducted by public laboratories and only phytosanitary inspections carried out by Federal, State, or county inspectors or agents may be used as the basis for issuing Federal phytosanitary certificates.

This service allows additional qualified personnel and laboratory facilities to conduct export certification activities, thus relieving some of the demands placed upon APHIS' limited resources, by increasingly stringent foreign import requirements, and dwindling Federal and State budgets.

This accreditation program necessitates the use of a number of information collection activities APHIS must engage in to ensure that the individuals and laboratory facilities participating in its export certification program have the necessary qualifications to do so.

2. Indicate how, by whom, 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.

Denial-Written Appeal and Request for Hearing (Business)

The Administrator may deny accreditation to, or withdraw the accreditation of, any non-government facility to conduct laboratory testing or phytosanitary inspection services upon a determination that the facility does not meet the criteria for accreditation or maintenance of accreditation. In the case of a denial, the operator of the facility will be informed of the reasons for the denial and may appeal the decision in writing to the Administrator within 10 days after receiving notification of the denial. The Administrator will grant or deny the appeal in writing as promptly as circumstances permit, stating the reason for his/her decision. If there is a conflict as to any material fact, a hearing will be held to resolve the conflict. Rules of practice concerning the hearing will be adopted by the Administrator.

Withdrawal-Appeal and Request for Hearing (Business)

In the case of withdrawal, before such action is taken, the operator of the facility will be informed of the reasons for the proposed withdrawal. The operator of the facility may appeal the proposed withdrawal in writing to the Administrator within 10 days after being informed of the reasons for the proposed withdrawal. The appeal must include all of the facts and reasons upon which the person relies to show that the reasons for the proposed withdrawal are incorrect or do not support the withdrawal of the accreditation of the facility. The Administrator will grant or deny the appeal in writing as promptly as circumstances permit, stating the reason for his or her decision. If there is a conflict as to any material fact, a hearing will be held to resolve the conflict.

Written Request to Eliminate Accredited Status (Business)

The Administrator will withdraw the accreditation of a non-government facility if the operator of the facility informs APHIS in writing that the facility wishes to terminate its accredited status.

Documentation of Corrective Action (State)

A non-government facility whose accreditation has been denied or withdrawn may reapply for accreditation using the application procedures. If the facility's accreditation was denied or withdrawn, the facility operator must include with the application written documentation specifying what actions have been taken to correct the conditions that led to the denial or withdrawal of accreditation.

Application for Accreditation (Businesses and State)

The operator/owner of a non-government facility seeking accreditation to conduct laboratory testing or phytosanitary inspection must submit an application to APHIS. The application must contain the legal name and full address of the facility; the name, address, telephone and fax number of the facility's operator; a description of the facility; and a description of the specific laboratory testing or phytosanitary inspection services for which the facility is seeking accreditation.

Agreement for Fulfilling Accreditation Procedures (Business and State)

Before APHIS assesses a non-government facility to determine if it meets its accreditation requirements, the operator/owner of the facility must sign an agreement with APHIS promising to supply any information needed for the evaluation of the facility, to pay the fees APHIS charges to conduct its assessment, and to accept the charges that will result from subsequent accreditation maintenance.

Documentation of Equipment (Business and State)

The equipment used in the non-government facility (microscopes, computers, etc.) must be calibrated and monitored so that they conform to APHIS' standards. This calibration and monitoring must be documented by facility personnel.

Quality Manual or Equivalent Documentation (Business)

The operator/owner of the non-government facility is responsible for maintaining a quality manual or similar documentation at the facility that describes the system in place for conducting laboratory testing and phytosanitary inspection services. The manual must be available for use by facility personnel performing this work.

Identity of Personnel and Subcontractor's Qualifications (Business and State)

The personnel employed at the non-government facility must be identified and must possess the training, education, or experience necessary to perform laboratory testing and phytosanitary inspection services. The operator/owner of the facility is responsible for acquiring and maintaining documentation concerning the training, education, and experience of facility personnel.

If the non-government facility uses a subcontractor to perform some of its testing and inspection services, the qualifications of this subcontractor must be documented and made available to APHIS upon request. The facility operator/owner is responsible for acquiring and maintaining this documentation.

Notification of changes in personnel (Business and State)

The facility operator/owner must notify APHIS whenever the facility undergoes any changes in personnel. This notification may be written, communicated via telephone, or via any other means of communication convenient to the facility's operator/owner.

Report Changes in Location, Ownership, Physical Plant Equipment or Other Conditions (Business)

The facility operator/owner must notify APHIS if the facility moves its operations to a new location, undergoes an ownership change, replaces equipment, or experiences any other change in conditions that existed at the time the facility received accreditation. This notification may be written, communicated via telephone, or via any other means of communication convenient to the facility's operator/owner.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, 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.

Application of Accreditation and Agreement to Fulfill Accreditation Procedures letters are automated and posted at: www.seedhealth.org

Documentation of equipment, quality manual or equivalent documentation, identity of personnel and subcontractor's qualifications, notification of changes in personnel, and report changes in location and ownership documents are prepared by the applicant for which APHIS has no control of them being automated.

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.

APHIS is the only Federal agency responsible for the establishment of a program which non-government facilities can become accredited to perform specific lab testing or phytosanitary inspections.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

APHIS has no small entities involved with this information collection.

6. Describe the consequences 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.

This information collection activity is the minimum needed to ensure that non-government facilities have the necessary resources to conduct export certification activities on APHIS' behalf. If these activities are not conducted properly, APHIS' export certification program will be compromised, causing a disruption in plant and plant product exports that could prove financially damaging to United States exporters.

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;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**

Denial-Written Appeal and Request for Hearing - If an Administrator denies accreditation to any non-government facility, the operator of the facility will be informed of the reasons for the denial and may appeal the decision in writing to the Administrator within 10 days after receiving notification of the denial.

- **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 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 recordkeeping, disclosure, or reporting form, 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, soliciting comments on the information collection prior to submission to OMB.

The following individuals were consulted during 2014:

Joe Deford
Chief Operating Officer
Indiana Crop Improvement Association.
7700 Stockwell Road
Lafayette, IN 47909
Phone: 765-523-2501

Connie Sandve
Seed Health Science Office Manager
Iowa State University
127 Seed Science Center
Ames, IA 50011
Phone: 515-294-6821

Jerry Flint
Biotech Affairs and Regulatory Director
Pioneer Hi-Bred Intl Inc
7307 NW 62 nd Avenue
Johnson, IA 50131
Phone: 515-270-5986

On Thursday, January 30, 2014, pages 4864-4865, APHIS published in the Federal Register, a 60-day notice seeking public comments on its plans to request a 3-year renewal of this collection of information. No comments from the public were received.

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 provided to respondents and the basis for the assurance in 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 and attitudes, religious beliefs, and others that are 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. Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated.

. Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.

See APHIS Form 71 for hour burden estimates.

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

The cost to the public was determined by multiplying the total number of burden hours times the wage per hour rate. APHIS estimates that the average hourly wage is \$38.00. $199 \times \$38.00 = \$7,562$.

\$38.00 is the hourly rate derived from the U.S. Department of Labor, Bureau of Labor Statistics May 2012 Report - Occupational Employment and Wages in the United States. See <http://www.bls.gov/news.release/pdf/ocwage.pdf>

13. Provide estimates of the total annual cost burden to respondents or recordkeepers resulting from the collection of information, (do not include the cost of any hour burden shown in items 12 and 14). The cost estimates should be split into two components: (a) a total capital and start-up 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, operation and maintenance, and purchase of services in connection with this program.

14. Provide estimates of annualized cost to the Federal government. 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 cost to the Federal Government is \$2,833.00. (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-I.

	Request ed	Progra m Change Due to New Statute	Progra m Change Due to Agency Discreti on	Change Due to Adjustm ent in Agency Estimate	Change Due to Potentia l Violatio n of the PRA	Previously Approved
Annual Number of Responses	57	0	0	-30	0	87
Annual Time Burden (Hr)	199	0	0	-101	0	300
Annual Cost Burden (\$)	0	0	0	0	0	0

The number of respondents decreased from 15 to 9, and the annual number of responses decreased from 87 to 57 since the previous collection. The total number of burden hours also decreased from 300 to 199. These adjustments are due to a decrease of businesses that did not request accreditation certification.

16. For collections of information whose results are planned to be published, outline plans for tabulation and publication.

APHIS has no plans to tabulate or publish the information APHIS is collecting.

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

There are no forms associated with this collection.

18. Explain each exception to the certification statement identified in the “Certification for Paperwork Reduction Act.”

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.