

Supporting Statement
Export Certification: Accreditation of Nongovernment Facilities
OMB No. 0579-0130

October 2020

A. JUSTIFICATION

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.

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.

APHIS is asking OMB to approve, for 3 additional years, its use of these information collection activities, associated with this program.

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.

APHIS uses the following information activities to ensure that individuals and laboratory facilities participating in the export certification program have the necessary qualifications to do so.

Application for Accreditation (State and Business) - 7 CFR 353.8 (b)(2)

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) - 7 CFR 353.8 (b)(3)

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) - 7 CFR 353.8 (b)(3)(iii)

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

Quality Manual or Equivalent Documentation (Business and State) - 7 CFR 353.8 (b)(3)(iii)

The facility must have a quality manual or equivalent documentation that describes the system in place at the facility for the conduct of the laboratory testing or phytosanitary inspection services for which the facility seeks accreditation. The manual must be available to, and in use by, the facility personnel who perform the services. The methods and procedures followed by the facility to conduct the laboratory testing or phytosanitary inspection services for which it seeks accreditation must be commensurate with those identified in the accreditation standards and must be consistent with or equivalent to recognized international standards for such testing or inspection.

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

7 CFR 353.8(b)(3)(iv)

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) - 7 CFR 353.8(b)(4)(v)

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) - 7 CFR 353.8(b)(4)(vi)

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.

Denial-Written Appeal and Request for Hearing (Business) - 7 CFR 353.8 (a)(2)(i)

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) - 7 CFR 353.8 (a)(2)(ii)

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) - 7 CFR 353.8 (a)(3)

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 (Business) - 7 CFR 353.8 (a)(4)

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.

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.

The Application for Accreditation and Agreement for Fulfilling Accreditation Procedures are electronic 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 and APHIS has no control over the automation of this documentation.

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 determined there are 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.

Withdrawal-Appeal and Request for Hearing - 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.

- **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.

APHIS recently consulted with the following individuals regarding this program. The consultation with each individual stakeholder occurred during quarterly conference calls. These calls are opportunity for APHIS to address operational and policy questions in regards to the accreditation program. There were no questions or concerns noted in reference to availability of data, frequency of collection, the clarity of instructions and, disclosure, or reporting.

Samantha Thomas
External Engagement Strategy Lead
Bayer Crop Science
800 N. Lindbergh Blvd., N building
Creve Coeur, MO 63147
Phone: 314-694-7289

Robin Pruisner
State Plant Regulatory Official

Iowa Department of Agriculture and Land Stewardship
State Laboratory Facility
2230 S. Ankeny Boulevard
Ankeny, IA 50023
Phone: 515-725-1465

Tracy Bruns
Accreditation Coordinator
Iowa State University Seed Science Center
2115 Osborn Dr
Ames, IA 50011
Phone: 515-294-6493

On Monday, July 20, 2020, pages 43810-43811, Vol. 85, No. 139, 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 were received from the public.

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

APHIS estimates the total annual cost to these respondents to be \$15,773.48. APHIS arrived at this figure by multiplying the hours of estimated response time (209 hours) by the estimated average hourly wage of the above respondents (\$51.32) and then multiplying the result (\$10,725.88) by 1.4706 to capture benefit costs.

(209 burden hours X \$51.32 estimated hourly wage = \$10,725.88 X 1.4706)

The estimated hourly rate of \$51.32 was derived from the U.S. Department of Labor, Bureau of Labor Statistics May 2020 Report - Occupational Employment and Wages in the United States. See <https://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. However, there are fees associated with obtaining an accreditation. There is a \$1,000 non-refundable deposit required by USDA-APHIS with the initial application. Accreditation fees for Options 1 and 2 are based on a sliding scale that accounts for the number of seed health tests, the number of crops for Phytosanitary Inspection, and the number of sites to be accredited within the organization. A minimum fee of \$3,000 is applied for each option, but the fee is reduced to \$2,000 for entities that apply for both options, 1 and 2. Flat fees of \$1,000 are applied for Options 3 and 4. Additional costs are covered by the entity for auditor fees and travel expenses.

There are also maintenance fees associated with the accreditation. An annual fee of 16.5 percent of the initial accreditation fee will be applied to cover annual reports and proficiency tests for accredited entities that are required every 2 years. USDA-APHIS requires that accreditation certificates be renewed every 3 years. Accredited entities must complete a new application form and submit it with a non-refundable processing fee of \$1,000.

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 \$20,136. (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.

N	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	54	0	0	0	0	54
Annual Time Burden (Hr)	209	0	0	0	0	209
Annual Cost Burden (\$)	0	0	0	0	0	0

There is no change in burden for the information collection renewal.

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 being collected.

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.

APHIS will display all expiration dates.

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.