SUPPORTING STATEMENT - OMB NO. 0579-0213
Agriculture Select Agent Services; Import and Transport Permits for Non-Select Materials

May 2019

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

APHIS revised the name of this information collection from "Select Agent Registration" to "Agriculture Select Agent Services; Import and Transport Permits for Non-Select Materials" to more accurately describe these information collection activities. Since the last submission of this information collection, the Centers for Disease Control (CDC) assumed full responsibility for assuring Paperwork Reduction Act compliance for a number of forms formerly included this information collection and in their information collection 0920-0576 which are specific to select agent activities authorized by the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (Pub. L. No. 107-188), This reinstatement request (to 0579-0213) reflects those changes, as it now assumes responsibility only for the forms and information collection requests set forth below.

A. Justification

1. Explain the circumstances that make the 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 of 2002 (the Act, 7 U.S.C. 8301 *et seq*.) authorizes the U.S. Department of Agriculture (USDA) to provide for the oversight of the importation, entry, and movement in the United States of animals, pests or diseases, or any material or tangible object that could harbor them. Under the Act, USDA regulates certain organisms, biological agents, toxins, vectors, and animal products that have the potential to pose a severe threat to animal health or to animal products through the risk of disease or pest introduction.

The Animal and Plant Health Inspection Service (APHIS) has the primary responsibility for implementing the provisions of the Act within USDA. APHIS regulations for these activities are contained in 9 CFR part 94 (animals or animal products), 9 CFR part 95 (animal by-products) and 9 CFR part 122 (organisms and vectors). The regulations require an individual or entity, unless specifically exempted under the regulations, to apply for and be granted, by APHIS, a permit authorizing specific import or transport activities for regulated materials prior to engaging in the activities.

The permit application process entails the use of forms designed to obtain critical information concerning individuals or entities seeking a permit, as well as the specific characteristics of the material to be permitted. This data is needed, in part, to allow APHIS to assess the risk of importing or transporting the material, as well as the biosecurity and biosafety mitigations in

place at the receiving location. This, in turn, enables APHIS to ensure that appropriate safeguard, containment, and disposal requirements commensurate with the risk of the materials are implemented during transport, import, and upon receipt to protect against the spread or introduction of disease.

APHIS is asking the Office of Management and Budget (OMB) to approve, for 3 years, its use of this information collection to assess the risk of transporting or importing the material(s), and ensure that appropriate safeguards, containment, and disposal requirements commensurate with the risk are implemented, to prevent the spread or introduction of disease.

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 critical information concerning businesses and not-for-profit organizations seeking to permit regulated materials, the specific characteristics of the materials, and biosafety and biocontainment safeguards in place at the receiving location. These data are needed, in part, to allow APHIS to assess the risk of transporting or importing the material(s), and ensure that appropriate safeguard, containment, and disposal requirements commensurate with the risk are implemented, to prevent the spread or introduction of disease.

9 CFR 121.18: Inspection of Facilities (Business and Not-for-Profit) (State and Local Government)

APHIS must be allowed to inspect any site at which activities regulated under the pertinent regulations are conducted and must be allowed to inspect and copy any records relating to the activities covered by APHIS' regulations. VS requires this information for certain permits as described further below.

9 CFR 121.6: Application for Permit to Import or Transport Controlled Material or Organisms or Vectors (VS 16-3 or equivalent) (Business)

Any individual or entity planning to import or engage in the interstate transportation of VS or overlap select agents or toxins must apply to APHIS for a permit to do so. The permit application asks for such information as the applicant's name, organization, address, telephone number, and the name of the individual who will receive and be responsible for the imported material; the name and address of the producer/shipper, a description of the material to be imported --including the country of origin and the country in which processing occurred; the quantity and frequency of the importation and the expected completion date; the proposed use of the imported material, the treatment the material underwent prior to being imported into the United States, and the method that will be used for disposing of the imported material.

9 CFR 121.6: Additional Information for Cell Cultures and their Products (VS 16-7 or equivalent) (Business)

This is a supplemental form to VS Form 16-3. It requests additional information concerning specific material that requires the use of cell cultures, including monoclonal antibodies, recombinant products, extracts, and viruses. This form asks for the cell line or reference number, the cell line's country of origin, the cell line's passage history or recombinant status, the type of culture media used for the cell line, the names of any animal pathogens studied in the laboratory where the cell line originated, the address of the laboratory where the material originated, and the potential use of the imported cells or products.

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.

The Import Permit Application (VS 16-3) and Additional Information for Cell Cultures and their Products (VS 16-7) are automated as fillable PDFs which can be electronically submitted to APHIS.

In addition, APHIS is establishing a new system titled *e-File* for CARPOL (Certification, Accreditation, Registration, Permitting, and Other Licensing) activities. This new system will strive to automate and potentially reduce burden for some of these information collection activities. The system is still being developed and business processes continue to be identified and mapped.

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 APHIS collects in connection with this program is not available from any other source, since APHIS is the only Federal agency responsible for controlling agricultural materials that present a threat to animal or plant health.

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

The information collected is the absolute minimum need to prevent the introduction or spread of disease. APHIS estimated that there are no small entities involved with this information collection.

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 the information was collected less frequently or not collected, APHIS' efforts to more aggressively prevent agricultural disease or adverse health impacts in the United States would be compromised.

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;**
- **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 can be generalized to the universe of study;**
- **Requiring the use of 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;**
- **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.**

There are no special circumstances requiring that the collection of information be conducted in a manner inconsistent with the guidelines established in 5 CFR 1320.5.

8. Describe efforts to consult with individuals 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 engaged in productive consultations with stakeholders through a customer satisfaction survey provided to permit applicants throughout 2017 (OMB approved under 0579-0334). Approximately 40 respondents gave feedback, generally split between praise (for ease of use, clarity of instructions, and overall responsiveness) and criticism (for delays in review, processing, and response to questions as well as improving the Web site). Most of these were general concerns rather than with the specific forms of burden addressed in this information collection.

APHIS also consulted with individual stakeholders regarding their views on the availability of data, frequency of collection, clarity of instructions and recordkeeping, disclosure, or reporting forms, and the data elements to be recorded, disclosed, or reported. Their views were consistent with those who completed the customer satisfaction survey.

Janet Peterson
University of Maryland, College Park
3115 Chesapeake Building
College Park, MD 20742
301-405-3975

Dr. Will McCauley, Director
Veterinary Biologics
Animal Health Institute
202-637-2440
wmccauley@ahi.org

Paul Rubock
Columbia University
630 West 168th Street
New York City, NY 10032
212-305-1506

On Wednesday, February 21, 2019, APHIS published in the Federal Register (Vol. 84, No. 35, pages 5407-5408), a 60-day notice seeking public comments on its plans to request a reinstatement of this collection of information. During that time, no comments 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 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 individuals from whom the information is requested, and any steps to be taken to obtain their consent.

This information collection activity will ask 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. Burden estimates were developed from discussions with researchers, as well as personnel at universities, research and development organizations, and diagnostic 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 these respondents to be $405,421.11. APHIS arrived at this figure by multiplying the total burden hours (6,055) by the estimated average hourly wage of the above respondents ($45.53) and then multiplying the result ($275,684.15) by 1.4706 to capture benefit costs.

The average hourly wage is based on salaries of State, and local government health care officials ($54.68, medical and health services managers) and professional scientific and technical service providers ($36.39, epidemiologists), as derived from the U.S. Department of Labor's Bureau of Labor Statistics May 2018 Report - Occupational Employment and Wages in the United States at: http://www.bls.gov/oes/current/oes_stru.htm.

According to DOL BLS news release USDL-18-1499, dated September 18, 2018 (see https://www.bls.gov/news.release/pdf/ecec.pdf), benefits account for 32 percent of employee costs, and wages account for the remaining 68 percent. Mathematically, total costs can be calculated as a function of wages using a multiplier of 1.4706.

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.

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.

An estimate of the annual cost to the Federal Government is $163,355.26. (See APHIS 79.)

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-1.

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	3,283	0	0	0	3,283	0
Annual Time Burden (Hr)	6,055	0	0	0	6,055	0
Annual Cost Burden ($)	0	0	0	0	0	0

This is a reinstatement of an information collection resulting in 3,283 responses and 6,055 total burden hours.

Since the last submission of this information collection, APHIS has greatly improved its outreach and permit processing which can be attributed to the increased number of respondents for the following burden activities resulting in an additional +2,266 responses and +3,948 hours.

- Inspection of Facilities (+64 responses, + 512 hours)
- Application for Permit to Import or Transport Controlled Material or Organisms or Vectors (VS 16-3) (+2,134 responses, +3,414 hours)
- Additional Information for Cell Cultures and Their Products (VS 16-7) (+68 responses, +22 hours)

The following burden activities are approved under CDC's information collection (0920-0576); therefore, they have been removed from this information collection submission resulting in –3,719 responses and –10,260 hours:

- Request for Expedited Access Approval Review (-3 responses, -9 hours)
- Application for Registration for Possession, Use, and Transfer of Select Agents and Toxins (APHIS/CDC 1) (-23 responses, -272 hours)
- Amendment to the Application for Registration (-651 responses, -651 hours)
- Request to Transfer Select Agents and Toxins (APHIS/CDC 2) (-468 responses, -936 hours)
- Report of Transfer of Proficiency Test (now APHIS/CDC 4B) (-3 responses, -3 hours)
- Report of Theft, Loss, or Release of Select Agent and Toxins (APHIS/CDC 3) (-210 responses, -315 hours)
- Reporting the Identification of a Select Agent or Toxin in a Clinical/Diagnostic Specimen (APHIS/CDC 4 A, B, and C) (-373 responses, -373 hours)
- Request for Exemption of Select Agents and Toxins for Public Health or Agricultural Emergency or Investigational Product (APHIS/CDC 5) (-3 responses, -3 hours)
- Appeal of Registration Denial, Surrender of Registration Certificate (-3 responses, -3 hours)
- Request of ID Select Agents or Toxins Contained in Specimens Presented for Diagnosis or Verification (now APHIS/CDC 4A) (-6 responses, -6 hours)
- Recordkeeping (-296 recordkeepers/responses, -149 recordkeeping hours/hours)
- Security Plan (-380 responses, -1,900 hours)
- Biosecurity/Biocontainment Plan (-380 responses, -3,040 hours)
- Request regarding a Restricted Experiment (-160 responses, -320 hours)
- Incident Response Plan (-380 responses, -1,900 hours)
- Training (-380 responses, -380 hours)

In addition, the use of the Application and Permit to Move Live Plants or Noxious Weeds (PPQ Form 526) is approved under 0579-0054 and 0579-0207; therefore, it has been removed from this information collection submission resulting in -18 responses and -3 hours.

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

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 OMB approval of the information collection, explain the reasons that display would be inappropriate.

APHIS will display the expiration date on the VS 16-7.

APHIS is requesting exemption for not displaying the expiration date on the VS Form 16-3 because it is used in multiple information collections (each with its own expiration date). However, APHIS is exploring the creation of a common form.

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

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

B. Collections of Information Employing Statistical Methods

No statistical methods will be used in connection with this information collection.