

SUPPORTING STATEMENT
Agriculture Organisms and Vectors; Import and Transport Permits
OMB NO. 0579-0213

TERMS OF CLEARANCE: Before this ICR is resubmitted, USDA should convert Form VS 16-3 to a common form. This form is currently associated with multiple information collections, each with different OMB approval expiration dates. APHIS and OIRA are currently developing procedures for creating and maintaining a consolidated intra-Agency common form ICR. Upon the form inclusion in the common form ICR upon its approval, the form will be updated with the appropriate PRA banners, ICR control numbers, and OMB approval expiration dates.

NOTE: APHIS revised the name of this information collection from “Agriculture Select Agent Services; Import and Transport Permits for Non-Select Materials” to “Agriculture Organisms and Vectors; Import and Transport Permits” to describe these information collection activities more accurately. Since the last submission of this information collection, APHIS reorganized its emergency services functions into a single branch, Emergency and Regulatory Compliance Services (ERCS), and moved responsibility for select agents and toxins regulation and oversight from Veterinary Services (VS) to ERCS. VS retains responsibility for regulating and overseeing the use of organisms and vectors as part of its Animal Products Import and Export unit. This renewal request reflects those changes, as it now assumes responsibility only for organisms and vectors burden in 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 (AHPA) of 2002 (7 U.S.C. 8301 *et seq.*) authorizes the U.S. Department of Agriculture (USDA) to oversee 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 AHPA, USDA regulates certain organisms, vectors, and animal products that could 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 AHPA within USDA. APHIS regulations for these activities are contained in 9 CFR part 94 (animals or animal products), 9 CFR part 95 (animal byproducts) and 9 CFR part 122 (organisms and vectors). There is also a requirement for 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 receipt of requested materials.

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 organisms and vectors, and ensure that appropriate safeguards, containment, and disposal requirements commensurate with the risk are implemented.

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 permits to import and transport regulated materials as well as regarding 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.

Inspection of Facilities; (9 CFR 121.18); (Business; Not-for-Profit; State)

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' organism and vector regulations.

Application for Permit to Import or Transport Controlled Material or Organisms or Vectors (VS Form 16-3 or equivalent); (9 CFR 121.6; 9 CFR 122.2; 9 CFR 122.3); (Business)

U.S. importers, both nonprofits and businesses, must submit an application in writing to APHIS for permission to import organisms or vectors into the United States, or transport organisms or vectors from one State, Territory, or the District of Columbia to another State, Territory, or the District of Columbia. The application contains the importer's name, address, telephone number, fax number, a description of the products to be imported, the quantity and frequency of importation, the proposed use of the material, a description of the applicant's facilities for handling the material, the qualifications of the technical personnel who will be working with the material, and a description of any processing the material may have undergone before entering

the United States. This information enables APHIS to scrutinize the products and determine what, if any, disease threat they may pose to the U.S. livestock population. If APHIS decides to issue an import permit, information on the VS 16-3 enables officials to determine the appropriate safeguarding measures for the importation. APHIS can then provide port and border personnel with appropriate clearance instructions.

Additional Information for Cell Cultures and their Products (VS Form 16-7 or equivalent): (9 CFR 121.6; 9 CFR 112.2; 9 CFR 122.3); (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 VS Form 16-3 Import Permit Application and VS Form 16-7 Additional Information for Cell Cultures and their Products, are automated as fillable PDFs and are housed on the APHIS Electronic Forms Library at:

VS Form 16-3: https://www.aphis.usda.gov/library/forms/pdf/VS_16_3.pdf

VS Form 16-7: https://www.aphis.usda.gov/library/forms/pdf/VS_16_7.pdf

These forms can be electronically submitted to APHIS via e-File and the VS Permitting Assistant, <https://efile.aphis.usda.gov/s/vs-permitting-assistant>. e-File, which automates and reduces burden, is currently being phased in, with some applicants submitting all the VS Form 16-3 information electronically.

The information technology system called Certification, Accreditation, Registration, Permitting, and other Licensing (CARPOL) was not developed and has been removed from this renewal.

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.

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

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 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 the following individuals concerning the information collection activities associated with this program. We discussed with them how we and they obtain the necessary data and how frequently; how much data is available; the convenience and clarity of reporting formats and other collection instruments. The respondents stated via email or phone that they had no concerns with any of these items and had no further recommendations.

Dr. Charles McGee, Associated Director, Virology *
Technical Development
Seqirus
475 Green Oak Parkway
Holly Springs, NC 27540
Phone number: (919) 577-5457
*Individual review and not provided on behalf of Seqirus

Dr. Rodger Main, Director
Iowa State University Veterinary Diagnostic Laboratory
College of Veterinary Medicine
Iowa State University
Ames, IA 50011
Phone number: (515) 294-6945
Email: rmain@iastate.edu

Cindy Mahon
Zoetis Inc
333 Portage Street
Kalamazoo, MI 49007
Phone number: (269) 359-4513
Email: Cindy.Mahon@Zoetis.com

On Tuesday, November 16, 2021, APHIS published in the Federal Register (86 FR 63329), a 60-day notice seeking public comments on its plans to request a 3-year approval of this collection of information. One comment from the public was received but contained no relevant comments or recommendations about the activities or burdens in this information collection.

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 the respondents for this collection to be \$435,702. This was computed by multiplying the hours of estimated response time (6,055) hours by the estimated average hourly wage of the respondents (\$49.66) of the respondents and then multiplying the result by 1.449 to capture benefit costs.

The average hourly wage used to calculate the estimate are for State, and local government health care officials (\$57.61, SOCC 11-9111; medical and health services managers) and professional scientific and technical service providers (\$41.71, SOCC 19-1041; epidemiologists). The rates were found at the U.S. Bureau of Labor Statistics website https://www.bls.gov/oes/current/oes_stru.htm.

According to DOL BLS news release USDL-22-0469 dated March 18, 2022 (see <https://www.bls.gov/news.release/pdf/ecec.pdf>), benefits account for 31 percent of employee costs, and wages account for the remaining 69 percent. Mathematically, total costs can be calculated as a function of wages, resulting in a multiplier of 1.449.

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.

See APHIS 79. An estimate of the annual cost to the Federal Government is \$191,509.

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

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

In this renewal, there are no changes in the estimated burden.

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 VS Form 16-3 and 16-7 are used in multiple APHIS information collections, each with different OMB approval expiration dates. It would not be impractical to include an ICR approval expiration date on the form at this time. APHIS and OIRA are currently developing procedures for creating and maintaining a consolidated intra-Agency common form ICR. Upon the form inclusion in the common form ICR upon its approval, the form will be updated with the appropriate PRA banners, ICR control numbers, and OMB approval expiration dates.

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

APHIS can 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.