SUPPORTING STATEMENT - OMB NO. 0579-0213
SELECT AGENTS REGISTRATION PROCESS
BIOTERRORISM ACT

April 2012

TERMS OF CLEARANCE
OMB ACTION: Comment filed on proposed rule
OMB Number: 0579-0389

COMMENT: When submitting a request for approval at the Final rule stage, the agency should request a revision of 0579-0213 and provide a thorough explanation of the program changes and adjustments to the collection that will occur as a result of the rulemaking.

The *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (Pub. L. No. 107-188) (the Act) provides for the regulation of certain biological agents and toxins that have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products. The Animal and Plant Health Inspection Service (APHIS) and the Centers for Disease Control and Prevention (CDC) have the primary responsibility for implementing the provisions of the Act within the Department of Agriculture (USDA) and for the Department of Health and Human Services (HHS), respectively.

Sections 201 and 212(a)(2) of the Act require a biennial review and republication of the select biological agent and toxin list, with revisions as appropriate in accordance with this law. See 42 U.S.C. 262 a(a)(2) and 7 U.S.C. 8401(a)(2), respectively. This **final rule** will implement the recommendations of the biennial review of the list. Furthermore, revision of these regulations will incorporate the recommendations developed as a result of Executive Order 13546, "Optimizing the Security of Biological Select Agents and Toxins in the United States," and Executive Order 13486, "Strengthening Laboratory Security in the United States" which requires that the Secretaries of Health and Human Services and Agriculture publish proposed regulations to establish risk-based tiering of the select agent list, and revise the regulations, rules, and guidance to accommodate a tiered select agent list, in addition to enhanced and strengthened biosecurity measures, no later than October 2012.

In addition, APHIS is proposing several smaller-scale changes to the regulations, including the addition of definitions and clarification of language concerning security, training, biosafety/ biocontainment, and incident response. These changes would increase the applicability and effectiveness of the select agent regulations and provide for enhanced program oversight ensuring a baseline standard to be consistently applied to all physical, facility, and personnel security.

Specifically, APHIS/CDC Form 1 has been significantly changed to meet the needs of the agencies and the public who complete the form. The changes will result in an increase of hours per response to complete the form. The increase in burden is discussed in Question 15.

APHIS is requesting a revision of 0579-0213 which will incorporate the burden that was reported at the proposed rule stage for the comment filed OMB Control Number 0579-0389.

Prior to publication of the final rule, the agency should provide to OMB a summary of all comments received on the proposed information collection and identify any changes made in response to these comments.

APHIS received 30 comments concerning the proposed rule. These comments are addressed in Question 8.

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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 Public Health Security and Bioterrorism Preparedness and Response Act of 2002 was signed into law June 12, 2002. This law is designed to prevent, prepare for and respond to bioterrorism and other public health emergencies. The law requires individuals possessing agents or toxins deemed a severe threat to animal or plant health, or to animal or plant products, to be registered with the Secretary of Agriculture unless they have been specifically exempted. The Act also requires regulations regarding registration of individuals who possess, use, or transfer these agents or toxins be promulgated not later than 180 days from the date of its enactment.

The registration process entails the use of a number of separate forms designed to obtain critical information concerning individuals or entities in possession of certain agents or toxins, as well as the specific characteristics of the agents or toxins --including name, strain, and genetic information. This data is needed, in part, to allow the USDA's Animal and Plant Health Inspection Service (APHIS) to determine the biosafety level of an entity as well as the entity's biosecurity situation. This, in turn, helps APHIS to ensure that appropriate safeguard, containment, and disposal requirements commensurate with the risk of the agent or toxin are present at the entity, thus preventing access to such agents and toxins for use in domestic or international terrorism.

Information to determine that individuals seeking to register have a lawful purpose to possess, use, or transfer agents or toxins will also be requested as part of the registration process.

Additionally, information required by the Department of Justice to perform required background checks will need to be submitted.

APHIS is asking OMB to approve, for 3 years, the use of these information collections, associated with its efforts to more closely regulate select agents or toxins that could be used to commit acts of domestic or international terrorism. The information collection and recordkeeping requirements contained in this Final Rule are pending approval by OMB pursuant

to the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) under control number 0579-0213. The paperwork contained in this rule will not be effective until approved by OMB.

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 in possession of certain agents or toxins, as well as the specific characteristics of the agents or toxins, including name, strain, and genetic information. These data are needed, in part, to allow APHIS to determine the biosafety and biocontainment level of an entity as well as the entity's security situation. This, in turn, helps APHIS to ensure that appropriate safeguard, containment, and disposal requirements commensurate with the risk of the agent or toxin are present at the entity, thus preventing access to such agents and toxins for use in domestic or international terrorism. APHIS will also request information to determine that individuals seeking to register have a lawful purpose to possess, use, or transfer agents or toxins.

Request for Expedited Access Approval Review (Business and Not-for-Profit) (State and Local Government)

APHIS may expedite the access approval for individuals upon a request by the responsible official and a showing of good cause. APHIS submits the entity request to the Department of Justice to perform the required background check.

Application for Registration for Possession, Use, and Transfer of Select Agents and Toxins (APHIS/CDC Form 1) (Business and Not-for-Profit) (State and Local Government)

This form is designed to assist entities in complying with their legal obligation of notifying the Secretary of the Department of Agriculture and registering with APHIS to use, possess, or transfer select agents or toxins. Information requested on this form includes the entity's name, address, and telephone number; the agent or toxin for which registration is being sought, a description of the proposed protocol designed for the agent or toxin, a description of the biosafety and biosecurity measures in place at the entity where the proposed work is to be done, and the name of the individual responsible for the entity. This form is also used when an entity wants to amend its application. Amendments document changes in events that occur subsequent to registration (replacement of the responsible official, changes in select agent activities).

Amendment to the Application for Registration (APHIS/CDC Form 1) (Business and Not-for-Profit)

This form is also used when an entity requests an amendment to its registration. Amendments document changes in events that occur subsequent to registration (replacement of the responsible official, changes in select agent activities, etc.).

Request to Select Agents and Toxins (APHIS/CDC Form 2) (Business and Not-for-Profit) (State and Local Government)

This form is used by entities to request authorization from APHIS or CDC to receive or send a select agent or toxin. A registered entity is required by regulation (7 CFR 331.16, 9 CFR 121.16, and 42 CFR 73.16) to file this form with either APHIS or CDC and obtain approval prior to transfer of a Select Agent(s) or toxin. The completion of this form creates a "paper trail" that enables APHIS and CDC to ensure that agents or toxins being moved from one location to another arrive, intact, at their intended destination point.

The final rule includes the removal of 10 USDA and 4 CDC select agents. Entities will no longer be required to complete a Form 2 for these organisms.

Report of Transfer of Proficiency Test (Business and Not-for-Profit) (State and Local Government)

A select agent or toxin that is contained in a specimen for proficiency testing may be transferred without prior authorization from APHIS or CDC provided that, at least 7 calendar days prior to the transfer, the sender reports to APHIS or CDC the select agent or toxin to be transferred and the name and address of the recipient.

The responsible official must report the identification and final disposition of select agents or toxins contained in specimens presented for proficiency testing. This report must be followed by submission of APHIS/CDC Form 4 within 90 days of receipt.

Report of Theft, Loss, or Release of Select Agents or Toxins (APHIS/CDC Form 3) (Business and Not-for-Profit) (State and Local Government)

An individual or entity must immediately notify APHIS or CDC upon discovery of the theft, loss, or release of a select agent or toxin causing occupational exposure or a release of a select agent or toxin outside of the primary barriers of the biocontainment area. The theft, loss, or release must be reported by telephone, facsimile, or e-mail. The following information must be provided:

- The name of the select agent or toxin and any identifying information (e.g., strain or other characterization information);
- An estimate of the quantity stolen, lost, or released;
- An estimate of the time during which the theft or loss occurred or the time and duration of the release;
- The environment into which the release occurred (e.g., in building or outside of building, waste system);
- The location (building, room) from which the theft, loss, or release occurred;
- The number of individuals potentially exposed at the entity;
- Actions taken to respond to the release; and
- Hazards posed by the release.

A completed APHIS/CDC Form 3 must be submitted within 7 calendar days after the discovery of theft, loss, or release of select agents or toxins. Thefts or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified.

The final rule includes the removal of 10 USDA and 4 CDC select agents. Entities will no longer be required to complete a Form 3 for these organisms.

Reporting the Identification of a Select Agent or Toxin from a Clinical/Diagnostic Specimen (APHIS/CDC Forms 4A, 4B, and 4C) (Business and Not-for-Profit) (State and Local Government)

The APHIS/CDC Form 4, Reporting the Identification of a Select Agent or Toxin, is used by clinical or diagnostic laboratories and other entities to notify APHIS or CDC of the identification of a select agent or toxin as the result of diagnosis, verification, or proficiency testing and of the final disposition of that identified agent or toxin.

Clinical or diagnostic laboratories and other entities that have identified select agents or toxins contained in a specimen presented for diagnosis or verification are required by regulation to report the identification within 7 calendar days to APHIS or CDC.

Request for Exemption of Select Agents and Toxins for Public Health or Agricultural Emergency or Investigational Product (APHIS/CDC Form 5) (Business and Not-for-Profit) (State and Local Government)

An individual or entity may apply for an exemption to the registration process. Information requested on this form includes the entity's name, address, and telephone number; the agent or toxin for which exemption if being sought, a description of the proposed protocol designed for the agent or toxin, a description of the biosafety and biosecurity measures in place at the entity where the proposed work is to be done, and an explanation concerning why the exemption should be granted.

Appeal of Registration Denial; Surrender of Registration Certificate (Business and Not-for-Profit) (State and Local Government)

If an individual's or entity's registration application is denied, or if they receive notification that their registration will be suspended or revoked, they may appeal this decision in writing to the Administrator. The appeal letter must state all of the reasons why the individual's or entity's registration should not be denied, suspended, or revoked. If an individual or entity is voluntarily surrendering their certificate of registration to the Animal and Plant Health Inspection Service, they must notify the agency of their intention to do so and provide the agency with any information that may be requested to verify that the individual or entity is no longer working with the agents or toxins of concern.

Report of Identification of Select Agents or Toxins Contained in Specimens Presented for Diagnosis or Verification [Letter] (business and Not-for-Profit) (State and Local Government)

The responsible official must report the identification and final disposition of select agents or toxins contained in specimens presented for diagnosis or verification once identified. This report must be followed by submission of APHIS/CDC Form 4 within 7 days of receipt.

Recordkeeping (Business and Not-for-Profit) (State and Local Government)

The records to be retained are needed to verify that laboratories/entities are maintaining efficient and reliable data to ensure that appropriate safeguard, containment, and disposal requirements are being followed. Records should be retained for 3 years. Entities would be required to maintain an accurate, current inventory of any animals or plants intentionally or accidentally exposed to or infected with a select agent (including number and species, location, and appropriate disposition).

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 this part are conducted and must be allowed to inspect and copy any records relating to the activities covered by APHIS' regulations.
Prior to issuing a certificate of registration to an individual or entity, APHIS may inspect and evaluate their premises and records to ensure compliance with APHIS' regulations.

Application for Permit to Import or Transport Controlled Material or Organisms or Vectors (VS 16-3) (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.

Additional Information for Cell Cultures and their Products (VS 16-7) (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, the type of culture media used for the cell line, the names of any animal viruses 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.

Application and Permit to Move Live Plants or Noxious Weeds (PPQ 526) (Business)

Any individual or entity planning to import or engage in the movement of PPQ select agents or toxins deemed a severe threat to plant health or plant products must apply to APHIS for a permit to do so. The permit application asks for such information as the applicant's name, organization, address, and telephone number; the type of agents or toxins to be moved and their scientific names, what kind of host material will accompany the agents or toxins, the shipment's port of arrival and destination within the United States, the approximate date of arrival or movement of the agents or toxins, the number of shipments, the supplier, the intended use of the agents or toxins, the methods that will be employed to prevent agent or toxin escape, and what method will be used to dispose of the agents or toxins.

Security Plan (Business and Not-for-Profit) (State and Local Government)

The rule would allow for the optimization of security measures for those select agents or toxins that present the greatest risk of deliberate misuse with the most significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence, i.e., Tier 1 select agents and toxins. Entities possessing a Tier 1 select agent or toxin must have a security plan describing procedures for determining the suitability of persons who would have access to a Tier 1 select agent or toxin; training on policies and procedures for evaluation and reporting concerning the assessment of personnel suitability to access Tier 1 agents and toxins; and the ongoing suitability monitoring of individuals with access to Tier 1 select agents and toxins. Furthermore, entities with Tier 1 select agents and toxins must have security enhancements that contain provisions for security barriers, intrusion detection and monitoring, delay/response force, and access control.

All entities must address information security measures within their security plans, including: network connectivity monitoring, restriction of user permissions to only mission-specific files and applications, measures to prevent network infiltration by malicious code, and configuration management including regular patching and system software updates. Entities would be required to establish consistent practices into a written standard for shipping, receiving, and storage of select agents and toxins to ensure that the entity has documented processes for securing and monitoring the shipment, receipt, and storage of these items.

Lastly, entities would be required to clearly state the provisions to address the safeguarding of animals or plants intentionally or accidentally exposed to or infected with select agents within their security plan. Entities would be required to submit their security plan for initial registration and renewals of registration, as well as at any other time upon request.

Biosafety/Biocontainment Plan (Business and Not-for-Profit) (State and Local Government)

The biosafety plan must include an occupational health program for individuals with access to Tier 1 select agents and toxins, and those individuals must be enrolled in the occupational health program.

Entities would be also be required to clearly state the provisions to address the safeguarding of animals or plants intentionally or accidentally exposed to or infected with select agents within their biosafety/biocontainment plan.

Request Regarding a Restricted Experiment (Business and Not-for-Profit) (State and Local Government)

Restricted experiments are those experiments that may not be performed by regulated entities without the approval of the Administrator. APHIS is also proposing to remove recombinant technology as a determining factor for a restricted experiment; all experiments involving the creation of drug resistant select agents must be submitted to the Select Agent Program for approval. In addition, APHIS is proposing to state that entities may not possess the products of restricted experiments without a request to, and approval from, the Administrator.

Incident Response Plan (Business and Not-for-Profit) (State and Local Government)

APHIS is proposing to specify that each entity's incident response plan be based upon a site-specific risk assessment. This change would further ensure the specificity and quality of the plan.

Additionally, entities would be required to clearly state the provisions to address the safeguarding of animals or plants intentionally or accidentally exposed to or infected with select agents within their incident response plan.

Training (Business and Not-for-Profit) (State and Local Government)

A record of the training provided to each individual must be maintained. Under the proposed rule, entities would be required to supplement current training practices with security awareness and incident response training, as well as provide adequate training to inform individuals of the changes when a registered entity's security, incident response, or biosafety/biocontainment plans have been substantively altered.

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 APHIS/CDC forms below can be found on the National Select Agent Registry at the Web site address as follows: http://www.selectagents.gov
Application for Registration for Possession, Use, and Transfer of Select Agents and Toxins (APHIS/CDC Form 1)

Request to Transfer Select Agents and Toxins (APHIS/CDC Form (APHIS/CDC Form 2)
Report of Theft, Loss, or Release of Select Agents and Toxins (APHIS/CDC Form 3)

Reporting the Identification of a Select Agent or Toxin in a Clinical or Diagnostic Specimen (APHIS/CDC Forms 4A, 4B, and 4C)

Request for Exemption of Select Agents and Toxins for Public Health or Agricultural Emergency or Investigational Product (APHIS/CDC Form 5)

The Import Permit Application (VS 16-3) is automated as a PDF and is downloadable at: http://www.aphis.usda.gov/library/forms/pdf/VS_16_3.pdf

Additional Information for Cell Cultures and their Products (VS 16-7) is automated as a PDF and is downloadable at: http://www.aphis.usda.gov/library/forms/pdf/VS_16_7.pdf

Application for Permit (PPQ 526) is automated as a PDF and is downloadable at: http://www.aphis.usda.gov/library/forms/pdf/PPQ_526.pdf

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 will be collecting in connection with this program is not available from any other source, since APHIS is the only Federal agency responsible for controlling agricultural select agents or toxins that present a potential but severe 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 has 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 a bioterrorism event 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;**

There are no requirements of quarterly reporting of information.

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

The responsible official must report the identification and final disposition of select agents or toxins contained in specimens presented for diagnosis or verification once identified. This report must be followed by submission of APHIS/CDC Form 4 within 7 days of receipt.

A select agent or toxin that is contained in a specimen for proficiency testing may be transferred without prior authorization from APHIS or CDC provided that, at least 7 calendar days prior to the transfer, the sender reports to APHIS or CDC the select agent or toxin to be transferred and the name and address of the recipient.
An individual or entity must immediately notify APHIS or CDC upon discovery of the theft, loss, or release of a select agent or toxin causing occupational exposure or a release of a select agent or toxin outside of the primary barriers of the biocontainment area. The theft, loss, or release must be reported by telephone, facsimile, or e-mail. The following information must be provided:

The name of the select agent or toxin and any identifying information (e.g., strain or other characterization information); an estimate of the quantity stolen, lost, or released; an estimate of the time during which the theft or loss occurred or the time and duration of the release; the environment into which the release occurred (e.g., in building or outside of building, waste system); the location (building, room) from which the theft, loss, or release occurred; the number of individuals potentially exposed at the entity; actions taken to respond to the release; and hazards posed by the release. A completed APHIS/CDC Form 3 must be submitted within 7 calendar days after the discovery of theft, loss, or release of select agents or toxins. Thefts or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified.

The APHIS/CDC Form 4, Report of the Identification of a Select Agent or Toxin, is used by clinical or diagnostic laboratories and other entities to notify APHIS or CDC of the identification of a select agent or toxin as the result of diagnosis, verification, or proficiency testing and of the final disposition of that identified agent or toxin.

Clinical or diagnostic laboratories and other entities that have identified select agents or toxins contained in a specimen presented for diagnosis or verification are required by regulation to report the identification within 7 calendar days to APHIS or CDC.

- **Requiring respondents to submit more than an original and two copies of any document;**

There are no requirements for 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;**

  As per the regulations, (7 CFR 331.17 and 9 CFR 331.17), an individual or entity required to register under this part, must maintain complete records relating to the activities covered by this part. All records created under this part must be maintained for 3 years and promptly produced upon request.

- **In connection with a statistical survey, that is not designed to produce valid and reliable results can be generalized to the universe of study;**

  There is no statistical survey associated with this information collection.

- **Requiring the use of statistical data classification that has not been reviewed and approved by OMB;**

  Any and all statistics data classification is always 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**
  There will be no pledge of confidentiality in this information collection.

- **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.**

  Respondents will not be required to submit proprietary trade secret, or other confidential information for this information collection.

There are no other 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 in 2012:

Dr. Kristina Peterman
American Type Culture Collection
10801 University Boulevard
Manassas, VA 20110
(703) 365-2700

Dr. David Swayne
Southeast Poultry Research Laboratory
934 College Station Road
Athens, GA 30605
(706) 546-4333

Dr. Jeffrey Field
Fort Dodge Animal Health, Division of Wyeth, LLC
2000 Rockford Road
Charles City, IA 50616
(641) 257-3352

APHIS' proposed rule (APHIS-2009-0070) was published in the Federal Register on Monday, October 3, 2011, with a 60-day comment period. During that time, APHIS received 30comments from interested members of the public, including researchers, scientific organizations, laboratories, and universities. Specifically, two commenters suggested the use of specific documents in creating guidance for meeting the requirements of the regulations. APHIS agreed and has utilized the recommended sources in developing guidance. Other commenters wanted some of the select agents removed from the regulations but APHIS did not agree with these requests and did not remove any of the agents. Other commenters requested clarification as to whether laboratories would be required to treat certain diseases as a select agent. Clarification has been added to the list of agents for these diseases. Some commenters expressed concern for the tier designations of select agents. APHIS has determined that the tier designations will remain unchanged because of the relative ease with which a particular select agent or toxin might be disseminated or transmitted from one animal, plant, or person to another or into the environment where it could produce a deleterious effect upon animal, plant, or human health. Two commenters recommended that the select agent program consult with administrators and laboratory managers for documents that address security concerns. APHIS responded that it welcomes feedback on the usability and usefulness of existing guidance documents at any time and provides the email address for those documents in the final rule. Some commenters requested additional definitions for certain select agents for clarification. Some of these recommendations have been added to the final rule. Another commenter asked that a timeline be added to the regulations indicating when a person should expect to receive a written response. APHIS decided that due to the wide variety of material submitted for consideration for exclusions, establishment of a timeline as the commenter recommends is impractical. A few commenters questioned the security requirements of the regulations. APHIS responded that guidelines concerning security requirements may be found on the National Select Agent Registry at www.selectagents.gov One commenter argued that the requirements for a written incident response plan was misleading. APHIS responded that the regulations are intended to prevent the theft, loss, or release of select agents and toxins and that guidance is available at the National

Select Agent Registry referenced above. Overall, APHIS is aware that a lack of adequate safety and security requirements could result in damages measured not only in dollars but in human lives. It is APHIS' determination, based on the information available to it, that the additional requirements would not constitute a significant economic or recordkeeping burden on the regulated entities. APHIS also believes that in many cases these regulations serve to codify systems and procedures already in use by a majority of regulated entities.

The proposed rule is being adopted as the **final** rule, with all changes discussed in the final rule. The comment filed OMB control number, 0579-0389 will be rescinded upon approval of the revision of 0579-0213.

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 above respondents to be $6,459,801. APHIS arrived at this figure by multiplying the total burden hours (12,368) by the estimated average hourly wage of the above respondents ($52.23). The average hourly wage is based on salaries of State, and local government, health care officials, and professional scientific and technical services.

$52.23 is the hourly rate derived from the U.S. Department of Labor, Bureau of Labor Statistics; National Compensation Survey: Occupational Wages in the United States, May 2009. See: http://www.bls.gov/news.release/ocwage.t.03.htm

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 $32,573. (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	4,754	0	3,335	255	0	1,164

Annual Time Burden (Hr)	12,368	0	9,823	255	0	2,290
Annual Cost Burden ($)	0	0	0	0	0	0

There is a program change of 386 additional respondents, 3,335 annual responses, and 9,823 hours. The reason for the program change is a result of final rulemaking that adds an Amendment to APHIS/CDC Form 1, recordkeeping for the State, a Security Plan, Biosafety/Biocontainment Plan, Request Regarding a Restricted Experiment, Incident Response Plan, and Training to this collection and for additional time required to complete APHIS/CDC Forms 1, 2, and 3 because more information has been added to these forms for the public to complete.

There is also an adjustment of +69 respondents, +255 annual responses, and +255 burden hours due to an increase in the number of State respondents completing APHIS/CDC Form 4, and an increase in the number of responses per respondent for this form.

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.

Since APHIS CDC Forms 1, 2, 3, 4 (A, B, and C), and 5 are used in one information collection, APHIS will display the OMB expiration date on these forms.

APHIS will display the expiration date on the PPQ 526 and VS 16-7 but is requesting exemption for not displaying the expiration date on the VS 16-3 form because it is used in 6 collections.

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.