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

October 2008

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 were 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 more 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.

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.

Application for Permit to Import or Transport Controlled Material or Organisms or Vectors (VS Form 16-3) (cleared under 0579-0015)

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 Form 16-7) (cleared under 0579-0094)

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.

Request for Expedited Access Approval Review

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 Laboratory Registration for Possession, Use, and Transfer of Select Agents and Toxins (APHIS/CDC Form 1)

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).

Report of Transfer of Select Agents and Toxins (APHIS/CDC Form 2)

Whenever one entity transfers select agents or toxins to another entity in the United States, individuals at the sending entity must complete a transfer form describing --among other things-- the material being transferred, the date of the shipment, the amount of material being transferred, the purpose of the transfer, and the destination of the material. The completion of this form creates a "paper trail" that enables USDA to ensure that agents or toxins being moved from one location to another arrive, intact, at their intended destination point.

Report of Transfer of Proficiency Test

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.

Report of Theft, Loss, or Release of Select Agents or Toxins (APHIS/CDC Form 3)

A registered or non-registered 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. Thefts or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified.

Report of the Identification of a Select Agent or Toxin in a Clinical or Diagnostic Laboratory (APHIS/CDC Form 4)

Diagnostic and clinical laboratories that are not registered with USDA must use APHIS/CDC Form 4 to alert APHIS that they are in possession of select agents or toxins deemed a severe threat to animal health, animal products, plant health, or plant products. These entities must then either transfer the agent or toxin to a registered entity, or dispose of the material as stipulated by regulation. In addition, the new reporting requirement requests the immediate reporting of specified select agents and toxins followed by completing the APHIS/CDC Form 4. Identification of the other select agents and toxins must be reported within 7 calendar days.

Individuals must report select agents and toxins contained in specimens presented for diagnosis or verification and also, report select agents and toxins presented for proficiency testing. However, a completed APHIS/CDC Form 4 is not required.

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

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

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 & 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.

Application and Permit to Move Live Plant Pests or Noxious Weeds (PPQ Form 526) (cleared under 0579-0054)

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.

Report of Identification of Select Agents or Toxins Contained in Specimens Presented for Diagnosis or Verification

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.

Report of Identification of Select Agents or Toxins Contained in Specimens Presented for Proficiency Testing

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 AHIS/CDC Form 4 within 90 days of receipt.

Recordkeeping

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.

Inspection of Facilities

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 of 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.

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 website address for each form is listed below:

Application For Laboratory Registration for Possession, Use, And Transfer of Select Agents and Toxins (APHIS/CDC Form 1):
http://www.selectagents.gov

Report of Transfer of Select Agents and Toxins (APHIS/CDC Form (APHIS/CDC Form 2):
http://www.selectagents.gov

Report of Theft, Loss, or Release of Select Agents and Toxins (APHIS/CDC Form 3):

http://www.selectagent.gov

Report of the Identification of a Select Agent or Toxin in a Clinical or Diagnostic Laboratory (APHIS/CDC Form 4): http://www.selectagent.gov

Request For Exemption of Select Agents and Toxins for Public Health or Agricultural Emergency or Investigational/Experimental Product (APHIS/CDC Form 5): http://www.selectagent.gov

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 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.

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 in 2008:

Barbara Fox-Nellis
University of Florida
226 Tigert Hall
Gainesville, FL 32611
(352) 392-6369

Krista Murray
University of Delaware
222 South Chapel Street
Newark, DE 19716
(302) 831-1433

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

On Monday, June 30, 2008, pages 36837-36838, APHIS published in the Federal Register, a 60-day notice seeking public comments on its plans to request a **3-year renewal** of this collection of information. No comments from the public were received.

9. Explain any decision to provide any payment or gift to respondents, other than reenumeration of contractors or grantees.

This information collection activity involves no payments or gifts to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

No additional assurance of confidentiality is provided with this information collection. However, the confidentiality of information is protected under 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 $38,625. APHIS arrived at this figure by multiplying the hours of estimated response time (1286) by the estimated average hourly wage of the above respondents ($31.25).

$31.25 is the hourly rate derived from the U.S. Department of Labor, Bureau of Labor Statistics June 2005 Report - National Compensation Survey: Occupational Wages in the United States, August 2006. See http://www.bls.gov/ncs/ocs/sp/ncbl0832.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.

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 $120,292. (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.

There is an adjustment increase of + 348 hours for this collection because of the increased number of respondents participating in the registration process and because the Inspection of Facilities requirement allowing APHIS to inspect and evaluate their premises and records to ensure compliance with APHIS' regulations was omitted from the last submission.

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.

If forms were to be discarded because of an outdated OMB expiration date, but otherwise usable, higher printing costs would be incurred by the Federal Government. Therefore, APHIS is seeking approval to not display the OMB expiration date on its forms.

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.