SUPPORTING STATEMENT - OMB NO. 0579-NEW
BIOTERRORISM PROTECTION ACT OF 2002; BIENNIEL PUBLICATION FO THE SELECT AGENT AND TOXIN LIST; REGULATORY AMENDMENTS

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* (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. 262a(a)(2) and 7 U.S.C. 8401(a)(2), respectively. This **proposed rule** would implement the recommendations of the third biennial review of the list. Furthermore, revision of these regulations would incorporate the recommendations developed as a result of Executive Order 13546, "Optimizing the Security of Biological Select Agents and Toxins 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 no later than October 2011.

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.

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.

Report of Identification of a Select Agent or Toxin (APHIS/CDC Form 4)

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. Completion of this form provides APHIS and CDC with information needed to maintain awareness of potential outbreaks and determine if further action is necessary.

The proposed regulations include the removal of 10 USDA and 4 CDC select agents. Entities will no longer be required to complete a Form 4 for these organisms.

Application for Registration (APHIS/CDC Form 1)

This form is designed to assist entities in complying with their legal obligation to notify the Secretaries of the USDA and HHS and register with APHIS and CDC to use, possess, or transfer select agents or toxins. Information to be requested on this form will include the new security measures for all entities and the optimized security measures proposed for Tier 1 agents, as well as some minor changes regarding biosafety and biocontainment measures in place at the entity. Registrations are renewed every three years.

Amendment to the Application for Registration (APHIS/CDC Form 1)

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.).

Security Plan

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

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

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

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

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.

Request to Transfer Select Agents and Toxins (APHIS/CDC Form 2)

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 proposed regulations include the removal of 10 USDA and 4 CDC select agents. Entities will no longer be required to complete a Form 2 for these organisms.

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. 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).

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

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 email. 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 proposed regulations include the removal of 10 USDA and 4 CDC select agents. Entities will no longer be required to complete a Form 3 for these organisms.

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 (http://www.selectagents.gov):

- Application for Laboratory Registration for Possession, Use, and Transfer of Select Agents and Toxins (APHIS/CDC Form 1)
- Report of Transfer of Select Agents and Toxins (APHIS/CDC Form 2)
- Report of Theft, Loss, or Release of Select Agents and Toxins (APHIS/CDC Form 3)
- Report of the Identification of a Select Agent or Toxin in a Clinical or Diagnostic Laboratory (APHIS/CDC Form 4)

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.

Although APHIS is the lead agency in communicating this information collection request to the public, both APHIS and CDC are responsible for collecting the information. This information is not available from any other source, as these agencies are the only Federal agencies responsible for controlling select agents or toxins that present a potential but severe threat to human or animal health, plant health, and animal or plant products.

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

The majority of affected entities are likely to be small, about 80 percent. The impact of the changes to the regulations is expected to be minimal, however. Any entity that possesses, uses,

or transfers listed select agents or toxins is required to comply with the select agent regulations, and would likely incur costs associated with that compliance. Some of the proposed changes to the regulations may impose an added time cost to measures already required for compliance, with respect to security, biocontainment/biosafety, and incident response plans, restricted experiment requests, and training and inventory records. However, APHIS does not require any specific form or template for these documents; the entity may design or modify them as they like, as long as the required information is present.

The proposed regulations include the removal of 10 USDA/APHIS and 4 CDC select agents. Entities will no longer be required to complete any APHIS/CDC Forms for these organisms, and this will reduce their time burden.

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 and CDC's 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;**

  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.

  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. 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.

Prompt receipt of this information is necessary in order to ensure timely prevention or mitigation of any possible bioterrorism event in the United States.

- **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;**

  As per the regulations, (7 CFR 331.17, 9 CFR 331.17 and 42 CFR 73.17), 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;**
- **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**

- **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 other special circumstances associated with this information collection.

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 2010:

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APHIS and CDC's proposed rule [(APHIS-2009-0070 and CDC-2011-0012) will describe its information gathering requirements, and also provide a 60-day comment period. During this time, interested members of the public will have the opportunity to provide APHIS with their input concerning the usefulness, legitimacy, and merit of the information collection activities APHIS is proposing.

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 for the combined USDA/APHIS and CDC estimates; separate agency estimates are included in their respective proposed rules. 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 $571,761.81. APHIS arrived at this figure by multiplying the total burden hours (10,947) 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.t03.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 $655,988. (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.

This is a new collection.

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, and 4 are used in two information collections, 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.