

Supporting Statement B

Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73)
(OMB Control No. 0920-0576) Expiration 10-31-2014

Revision

Centers for Disease Control and Prevention (CDC)
Office of Public Health Preparedness and Response
Division of Select Agents and Toxins

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July 30, 2012

B. Collections of Information Employing Statistical Methods

Statistical methods will not be used for these data. Entities that possess, use, and transfer these agents must register with the Federal Select Agent Program.

1. Respondent Universe and Sampling Methods

The Federal Select Agent Program's respondents consist of local, state, federal, private and academic entities. Over the past three years, the sample size has increased from two hundred sixty four entities to three hundred twenty entities. CDC expects a one hundred percent response rate to the Application for Registration (Form 1) all entities wishing to possess, use, or transfer are required by regulations to register with either CDC or U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS). The Application for Registration (42 CFR, 73.7(d)) requests facility information; a list of select agents or toxins including the characterization of the select agent or toxin that the entity wishes to possess; and laboratory information. Prior to any change (e.g., adding or removing personnel changes, changes in ownership or control of the entity, changes in the activities involving any select agents or toxins, or the addition or removal of select agents or toxins), the Responsible Official must apply for an amendment to a certificate of registration by submitting the relevant page(s) of the Application for Registration **Attachment 5** (APHIS/CDC Form 1). CDC expects that each registered entity will amend their registration at least once. The response rate of the remaining forms, Request to Transfer Select Agent or Toxin; Report of Theft, Loss, or Release of Select Agent or Toxin; and Report of Identification of Select Agent or Toxin may vary as they are only provided by the entities when there is a need to transfer a select agent or toxin, report a theft, loss or release of a select agent or toxin and when an entity identifies a select agent or toxin contained in a specimen presented for diagnosis, verification, or proficiency testing. This submission period CDC expects the following number of responses per entity: Request to Transfer Select Agent or Toxin (1); Report of Theft, Loss, or Release of Select Agent or Toxins (1); and Report of Identification of Select Agent or Toxin (9).

2. Procedure for the Collection of Information

DSAT has implemented an electronic data collection system that uses electronic forms,

which are available on the Federal Select Agent Program website at <http://www.selectagents.gov/Forms.html> in a pdf-fillable format for electronic submission. The use of a pdf-fillable format, allows respondents to save the document to their local drive, complete the form, and then upload the form to CDC. This approach supports data entry security; eliminating the possibility of another entity overwriting the submission. The entity can retain an electronic copy of their submission, which will make it easier for the entity to amend any future submissions. This information collection does not require interviews or anyone to administer questions.

3. Methods to Maximize Response Rates and Deal with No response

Currently, entities use of forms to request the possession and use of select agents and toxins or any changes to the entity's registration and transfer of select agents and toxins and report the theft, loss or release of a select agent or toxin and the identification of a select agent or toxin contained in a specimen presented for diagnosis, verification, or proficiency testing. The forms can be sent to CDC via mail, phone and fax. Response rates have been maximized by implementing an electronic data collection system that uses electronic forms, which are available on the Federal Select Agent Program website at <http://www.selectagents.gov/Forms.html> in a pdf-fillable format for electronic submission. The Select Agent Regulations requires entities to register the possession of select agents and toxins, request to transfer select agents and toxins; and report the theft, loss or release of a select agent or toxin and the identification of a select agent or toxin contained in a specimen presented for diagnosis, verification, or proficiency testing. If the entity fails to comply with the regulations, the entity may be referred to HHS Office of Inspector General for violation of the select agent regulations and subject to civil monetary penalties.

4. Test of Procedures or Methods to be Undertaken

The revisions to Application for Registration are associated with the proposed rule Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73); Rule Identification Number RIN 0920-AA34; Docket No. CDC-2011-0012 CDC/DSAT conducted pilot testing with four entities to determine estimates of annualized burden hours and cost. The Application for Registration (Form 1) was disseminated to four CDC/DSAT

entities to determine burden and improve utility. Each entity received identical APHIS/CDC Application for Registration (Form 1) via email and was asked to provide feedback in fourteen days. Burden hours were determined by measuring the time taken by the respondents to complete the APHIS/CDC Application for Registration (Form 1) by each of the entities and calculating the average. The proposed data collection instruments have been in previous projects (OMB Control No.0920-0576) Expiration 10-31-2014.

5. Individuals Consulted on Statistical Aspects and individuals Collecting and/ or Analyzing Data.

Statistical methods will not be used for Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73) (OMB Control No. 0920-0576). Therefore, a consultant was not required to address statistical aspects of the design of this project. The following representatives from APHIS assisted with the development of the data collection instruments:

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