Supporting Statement B

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

Revision

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

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B. Collections of Information Employing Statistical Methods

This collection of information does not employ statistical methods. The data collection is mandated by 42 CFR 73.

1. Respondent Universe and Sampling Methods

Not applicable because this collection of information does not employ statistical methods, as described above. All entities or individuals are mandated to submit information as outlined by 42 CFR 73.

2. Procedures 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 Federal Select Agent Program. 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.

The following forms or data collections will be used:

Request for Exclusion - An attenuated strain of a select agent or a select toxin modified to be less potent or toxic may be excluded from the requirements of this part based upon a determination by the HHS Secretary that the attenuated strain or modified toxin does not pose a severe threat to public health and safety (42 CFR 73.3 and 4 (e)). CDC has not developed standardized forms to use in the above situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation.

Report of the Identification of a Select Agent or Toxin Form is used by clinical or diagnostic laboratories and other entities to notify the Federal Select Agent Program 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.

The APHIS/CDC Form 5, Request for Exemption Form is used by an entity to request an exemption from the Select Agents Regulations for an investigational product.

The Application for Registration (42 CFR, 73.7(d)) is used by entities to register with FSAP. The Application for Registration requests facility information; a list of select agents or toxins in use, possession, or for transfer by the entity; characterization of the select agent or toxin; and laboratory information. This form is also used by the entity to amend their registration (42 CFR, 73.7(h) (1)) if any changes occur in the information submitted. When applying for an amendment to a certificate of registration, an entity must obtain the relevant portion of the application

package and submit the information requested in the package to FSAP.

The Amendment to a Certificate of Registration Form allows entities to make amendments to prior registration information.

The Documentation of Self-inspection Form - Prior to issuance of a certificate of registration, CDC inspects entities to ensure compliance with this regulation (42 CFR 73.18). As part of the inspection process, the entity may need to respond to written requests from CDC.

The Request for Expedited Review - An entity may apply to the HHS Secretary for an expedited review of an individual by the Attorney General (42 CFR 73.10(e)). To apply for this expedited review, an entity must submit a request in writing to the HHS Secretary establishing the need for such action. CDC has not developed standardized forms to use in the above situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation.

Security Plan - An individual or entity required to register under this part must develop and implement a written security plan. The security plan must be sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release (42 CFR 73.11(a)). CDC has not developed standardized forms to use in the above situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation.

Biosafety Plan - An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent (42 CFR 73.12(a)). CDC has not developed standardized forms to use in the above situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation.

Request Regarding a Restricted Experiment - An individual or entity may not conduct, or possess products resulting from, the following experiments unless approved by and conducted in accordance with the conditions prescribed by the HHS Secretary:

(1) Experiments that involve the deliberate transfer of, or selection for, a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture.

(2) Experiments involving the deliberate formation of synthetic or recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight (42 CFR 73.13 (a)). CDC has not developed standardized forms to use in the above situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation.

Incident Response Plan - An individual or entity required to register under this part must develop

and implement a written incident response plan based upon a site specific risk assessment. The incident response plan must be coordinated with any entity-wide plans, kept in the workplace, and available to employees for review (42 CFR 73.14 (a)). CDC has not developed standardized forms to use in the above situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation.

Training - The Responsible Official must ensure a record of the training provided to each individual with access to select agents and toxins and each escorted individual (e.g., laboratory workers, visitors, etc.) is maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training (42 CFR 73.16(d)). CDC has not developed standardized forms to use in the above situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation.

The Request to Transfer Select Agent or Toxin form (42 CFR 73.16) is used by entities requesting pre-authorization from FSAP to receive or send a select agent or toxin.

Records - An individual or entity required to register under this part must maintain complete records relating to the activities covered by the select agent regulations (42 CFR 73.17 (a)). CDC has not developed standardized forms to use in the above situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation.

The Report of Theft, Loss, or Release of Select Agent or Toxin form (42 CFR 73.19(a) (b)) is completed by entities whenever there is theft, loss, or release of a select agent or toxin.

Administrative review - An individual or entity may appeal a denial, revocation, or suspension of registration under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the HHS Secretary within 30 calendar days of the decision. An individual may appeal a denial, limitation, or revocation of access approval under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the HHS Secretary within 180 calendar days of the decision. (42 CFR 73.20 (a) and (b)). CDC has not developed standardized forms to use in the above situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Currently, entities' use of forms to request the possession and use of select agents and toxins or any changes to the entity's registration, transfer of select agents and toxins, report the theft, loss or release of a select agent or toxin and report 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 Federal Select Agent Program via mail, phone and fax. Response rates have been maximized by implementing an electronic data collection system that uses pdf-fillable format for electronic submission. 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. Tests of Procedures or Methods to be Undertaken

CDC has not conducted any tests of procedures.

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.

Records maintained in the National Select Agent Registry (NSAR), a joint DSAT and U.S. Department of Agriculture/Animal and Plant Health Inspection Service (APHIS) information management system, are accessed by DSAT staff for data entry, data query, and routine reporting activities.