



**BILLING CODE: 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[60Day-15-0576]**

**[Docket No. CDC-2015-0013]**

**Proposed Data Collection Submitted for Public Comment and Recommendations**

**AGENCY:** Centers for Disease Control and Prevention (CDC),  
Department of Health and Human Services (HHS)

**ACTION:** Notice with comment period

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed revision of the

information collection entitled *Possession, Use, and Transfer of Select Agents and Toxins* (OMB Control No. 0920-0576). CDC is requesting Office of Management and Budget (OMB) approval to continue to collect information under the select agent regulations through the use of five forms: 1) Application for Registration for Possession, Use, and Transfer of Select Agents and Toxins (APHIS/CDC Form 1); 2) Request to Transfer Select Agents or Toxins (APHIS/CDC Form 2); 3) Incident Form to Report Potential Theft, Loss, Release, or Occupational Exposure (APHIS/CDC Form 3); 4) Report of Identification of Select Agent or Toxin from Clinical/Diagnostic Specimen, Proficiency Testing, or Seizure by Federal Law Enforcement (APHIS/CDC Form 4); and 5) Request for Exemption of Select Agents and Toxins for an Investigational Product (APHIS/CDC Form 5).

**DATES:** Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2015-0013 by any of the following methods:

- Federal eRulemaking Portal: [Regulation.gov](http://www.Regulation.gov). Follow the instructions for submitting comments.

- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

**Instructions:** All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to [Regulations.gov](https://www.regulations.gov), including any personal information provided. For access to the docket to read background documents or comments received, go to [Regulations.gov](https://www.regulations.gov).

Please note: All public comment should be submitted through the Federal eRulemaking portal ([Regulations.gov](https://www.regulations.gov)) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: [omb@cdc.gov](mailto:omb@cdc.gov).

**SUPPLEMENTARY INFORMATION:**

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the

Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or

provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

### **Proposed Project**

Possession, Use, and Transfer of Select Agents and Toxins (OMB Control No. 0920-0576, Expiration - 11/30/2015) - Revision - Office of Public Health Preparedness and Response (OPHPR), Centers for Disease Control and Prevention (CDC).

### **Background and Brief Description**

Subtitle A of the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, (42 U.S.C. 262a), requires the United States Department of Health and Human Services (HHS) to regulate the possession, use, and transfer of biological agents or toxins that have the potential to pose a severe threat to public health and safety (select agents and toxins). Subtitle B of the Public Health Security and

Bioterrorism Preparedness and Response Act of 2002 (which may be cited as the *Agricultural Bioterrorism Protection Act of 2002*), (7 U.S.C. 8401), requires the United States Department of Agriculture (USDA) to regulate the possession, use, and transfer of biological agents or toxins that have the potential to pose a severe threat to animal or plant health, or animal or plant products (select agents and toxins). Accordingly, HHS and USDA have promulgated regulations requiring individuals or entities that possess, use, or transfer select agents and toxins to register with the CDC or the Animal and Plant Health Inspection Service (APHIS). See 42 C.F.R. Part 73, 7 C.F.R. Part 331, and 9 C.F.R. Part 121 (the select agent regulations). The Federal Select Agent Program (FSAP) is the collaboration of the CDC, Division of Select Agents and Toxins (DSAT) and the APHIS Agriculture Select Agent Services (AgSAS) to administer the select agent regulations in a manner to minimize the administrative burden on persons subject to the select agent regulations. The FSAP administers the select agent regulations in close coordination with the Federal Bureau of Investigation's Criminal Justice Information Services (CJIS). Accordingly, CDC and APHIS have adopted an identical system to collect information for the possession, use, and transfer of select agents and toxins.

CDC is requesting OMB approval to continue to collect information under the select agent regulations through the use of five forms: 1) Application for Registration for Possession, Use, and Transfer of Select Agents and Toxins (APHIS/CDC Form 1); 2) Request to Transfer Select Agents or Toxins (APHIS/CDC Form 2); 3) Incident Form to Report Potential Theft, Loss, Release, or Occupational Exposure (APHIS/CDC Form 3); 4) Report of Identification of Select Agent or Toxin from Clinical/Diagnostic Specimen, Proficiency Testing, or Seizure by Federal Law Enforcement (APHIS/CDC Form 4); and 5) Request for Exemption of Select Agents and Toxins for an Investigational Product (APHIS/CDC Form 5).

An entity may amend its registration (42 CFR 73.7(h)(1)) if any changes occur to the information previously submitted to CDC. When applying for an amendment to a certificate of registration, an entity would complete the relevant portion of the application package (APHIS/CDC Form 1).

Besides the forms listed above, there is no standard form for the following information:

1. An individual or entity may request an exclusion from the requirements of the select agent regulations of an attenuated strain of a select agent or a select toxin modified to be less potent or toxic. (42 CFR 73.3(e) and 73.4(e)).

2. Annual inspections that are conducted by the entity must be documented. (42 CFR 73.9(a)(6)).
3. An individual's security risk assessment may be expedited upon written request by a Responsible Official and a showing of good cause. (42 CFR 73.10(f)).
4. An individual or entity may request approval to perform a "restricted experiment" (42 CFR 73.13).
5. An individual or entity must develop and implement a written security plan, biosafety plan, and incident response plan (42 CFR 73.11(a), 42 CFR 73.12(a), and 42 CFR 73.14(a)).
6. The Responsible Official at the must ensure a record of the training for each individual with access to select agents and toxins and each escorted individual is maintained (42 CFR 73.15(d)).
7. An individual or entity may appeal a denial, revocation, or suspension of registration. (42 CFR 73.20(a)).
8. An individual may appeal a denial, limitation, or revocation of access approval. (42 CFR 73.20(b)).

The total estimated annualized burden for all data collection was calculated using data obtained from the FSAP

database and is estimated as 8,528 hours. Information will be collected via fax, email and hard copy mail from respondents. Upon OMB approval, CDC will begin use of the revised forms in November 2015 through November 2018. There is no cost to the respondents.

Estimated Annualized Burden Hours

Section	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
73.3 & 73.4	Request for Exclusions	3	1	1	3
73.5 & 6	Report of Identification of a Select Agent or Toxin	303	3	1	909
73.5 & 73.6	Request of Exemption	1	1	1	1
73.7	Application for Registration	5	1	5	25
73.7	Amendment to a Certificate of Registration	277	7	1	1,939
73.9	Documentation of self-inspection	277	1	1	277
73.10	Request for Expedited Review	1	1	30/60	1
73.11	Security Plan	277	1	5	1,385

73.12	Biosafety Plan	277	1	5	1,385
73.13	Request Regarding a Restricted Experiment	20	2	1	40
73.14	Incident Response Plan	277	1	5	1,385
73.15	Training	277	1	1	277
73.16	Request to Transfer Select Agents and Toxins	156	2	1	312
73.17	Records	277	1	30/60	139
73.19	Notification of Theft, Loss, or Release	215	2	1	430
73.20	Administrative Review	5	4	1	20
Total					8,528

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