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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-17-0576]

[Docket No. CDC-2016-0125]

**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 effort 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 CDC information collection project entitled "Possession, Use, and Transfer of Select Agents and Toxins."

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-2016-0125 by any of the following methods:

- Federal eRulemaking Portal: Regulations.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, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comments should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION: 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; Email: 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 is 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 to respond to a collection of information, search data sources, and 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 (42 CFR 73) (OMB Control No. 0920-0576, exp. 12/31/2018) - 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). The HHS Secretary delegated the responsibility for promulgating and implementing select agent regulations found at 42 C.F.R. Part 73 to CDC Division of Select Agents and Toxins (DSAT). The Animal and Plant Health Inspection Service (APHIS)/ Agriculture Select Agent Services (AgSAS) was delegated responsibility by USDA for select agent regulations (7 C.F.R. Part 331, and 9 C.F.R. Part 121). The Federal Select Agent Program (FSAP) is the collaboration of the DSAT and AgSAS to administer the select agent regulations in a manner to minimize the administrative burden on persons subject

to the select agent regulations. 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 revise the collected information under the select agent regulations through the use of the APHIS/CDC Form 3 (Report of Theft, Loss, or Release of Select Agents and Toxins). The Report of Theft, Loss, or Release of Select Agent and Toxin form (42 CFR 73.19(a), (b)) must be completed by an individual or an entity whenever the individual or entity experiences a theft, loss, or release of a select agent or toxin.

CDC is proposing to revise the form to further clarify what needs to be reported as a "release" and "loss" and additional fields to assist with categorizing the type of release (e.g., spill within secondary containment, occupational exposure, possible breach of facility containment, etc.), type of exposure, and the understanding of safety and security risk levels relative to human illness. Estimated average time to complete this form is one hour.

The total estimated annualized burden for this collection was calculated using data obtained from the FSAP database and is estimated as 430 hours. Information will be collected via fax, email and hard copy mail from respondents. Upon OMB approval,

CDC will continue use of the revised form through November 2018.

There is no cost to the respondents.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
73.19 Section	Report of Theft, Loss, or Release of Select Agents and Toxins	215	1	2	430
Total					430

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Office of Scientific Integrity
Office of the Associate Director for Science
Office of the Director
Centers for Disease Control and Prevention

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