Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-17-0576]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of

the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73) – Revision - Centers for Disease Control and Prevention (CDC)/Division of Select Agents and Toxins (DSAT) and United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS)/ Agriculture Select Agent Services (AgSAS).

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 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 United States Department of Agriculture (USDA) 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 (Incident Notification and Reporting (Theft/Loss/Release)). The 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. Guidance documents were also added to assist with the following forms: Application for Registration (APHIS/CDC Form 1), Request to Transfer Select Agents and Toxins (APHIS/CDC Form 2), Report of Identification of a Select Agent or Toxin (APHIS/CDC Form 4), Request of Exemption of Select Agents and Request for Exclusions Toxins for an Investigational Product (APHIS/CDC Form 5), Request for

Expedited Review, Security Plan, Security Plan, Biosafety Plan, Request Regarding a Restricted Experiment, Incident Response Plan, Training, and Records.

Annualized burden hours and cost were calculated based on data obtained from 2016 Annual Report of the Federal Select Agent Program for submissions to FSAP for 2016. CDC requests a three year approval for this Revision. The estimated annualized Burden has been reduced to 8,408 hours due to the decrease in the number of Respondents. There is no cost to Respondents other than their time.

Estimated Annualized Burden Hours

Section	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
73.7	Application for Registration (APHIS/CDC Form 1)	1	1	4
73.7	Amendment to a Certificate of Registration	238	7	1
73.7	Application for Registration (APHIS/CDC Form 1) Guidance	1	1	1
73.16	Request to Transfer Select Agents and Toxins (APHIS/CDC Form 2)	188	1	1
73.16	Request to Transfer Select Agents and Toxins (APHIS/CDC Form 2) Guidance	188	1	30/60
73.19	Report of Theft, Loss, or Release of Select Agent or Toxin (APHIS/CDC Form 3)	205	1	90/60
73.19	Report of Theft, Loss, or Release of Select Agent or Toxin (APHIS/CDC Form 3) Guidance	205	1	30/60
73.5 & 6	Report of Identification of a Select Agent or Toxin from a Clinical/Diagnostic Specimen (APHIS/CDC Form 4A)	1,030	1	30/60
73.5 & 6	Report of Identification of a Select Agent or Toxin from a Proficiency Test (APHIS/CDC Form 4B)	10	1	30/60
73.5 & 6	Federal Law Enforcement Reporting Seizure of Select Agent or Toxin (APHIS/CDC Form 4C)	1	1	30/60
73.5 & 6	Report of Identification of a Select Agent or Toxin (APHIS/CDC Form 4) Guidance	1,030	1	30/60
73.5 & 73.6	Request of Exemption of Select Agents and Toxins for an Investigational Product (APHIS/CDC Form 5)	1	1	30/60

73.5 & 73.6	Request of Exemption of Select Agents and Toxins for an Investigational Product (APHIS/CDC Form 5) Guidance	1	1	30/60
73.3 & 73.4	Request for Exclusions	3	1	30/60
73.3 & 73.4	Request for Exclusions Guidance	3	1	30/60
73.9	Documentation of Self-inspection	238	1	1
73.1	Request for Expedited Review	1	1	15/60
73.1	Request for Expedited Review Guidance	1	1	15/60
73.11	Security Plan	238	1	5
73.11	Security Plan Guidance	238	1	30/60
73.11	Security Plan Template	238	1	30/60
73.12	Biosafety Plan	238	1	5
73.12	Biosafety Plan Guidance	238	1	30/60
73.12	Biosafety Plan Template	238	1	30/60
73.13	Request Regarding a Restricted Experiment	1	1	30/60
73.13	Request Regarding a Restricted Experiment Guidance	1	1	30/60
73.14	Incident Response Plan	238	1	5
73.14	Incident Response Plan Guidance	238	1	30/60
73.14	Incident Response Plan Template	238	1	30/60
73.15	Training	238	1	30/60
73.15	Training Guidance	238	1	30/60
73.17	Records	238	1	30/60
73.17	Guidance on the Inventory of Select Agents	238	1	30/60
73.20	Administrative Review	1	1	1

_____

Leroy A. Richardson,
Chief, Information Collection Review Office,
Office of Scientific Integrity,
Office of the Associate Director for Science,
Office of the Director,
Centers for Disease Control and Prevention.

[FR Doc. 2017-16333 Filed: 8/2/2017 8:45 am; Publication Date: 8/3/2017]