DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–08–0576]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov.*

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; and (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. Written comments should be received within 60 days of this notice.

Proposed Project

Possession, Use, and Transfer of Select Agents and Toxins (OMB Control No. 0920–0576)—Extension—Division of Select Agents and Toxins (DSAT), Coordinating Office for Terrorism Preparedness and Emergency Response (COTPER), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Subtitle A of Public Law 107–188 (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 (i.e., select agents and toxins) that could pose a severe threat to public health and safety. The Agricultural Bioterrorism Protection Act of 2002, Subtitle B of Public Law 107–188 (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 (i.e., select agents and toxins) that could pose a severe threat to animal or plant health, or animal or plant products. In accordance with these Acts, HHS and USDA promulgated regulations requiring entities to register with the CDC or the Animal and Plant Health Inspection Service (APHIS) if they possess, use, or transfer a select agent or toxin (42 CFR part 73, 7 CFR part 331, and 9 CFR part 121). CDC and APHIS coordinate regulatory activities for those agents that would be regulated by both agencies (''overlap'' select agents). Accordingly, CDC and APHIS adopted an identical system to collect information for the possession, use, and transfer of select agents and toxins.

CDC is requesting continued OMB approval to collect this information through the use of five separate forms. These forms are: (1) Application for Registration, (2) Request to Transfer Select Agent or Toxin, (3) Report of Theft, Loss, or Release of Select Agent and Toxin, (4) Report of Identification of Select Agent or Toxin, and (5) Request for Exemption.

The Application for Registration (42 CFR, 73.7(d)) will be used by entities to register with CDC. 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. Estimated average time to complete this form is 3 hours, 45 minutes for an entity with one principal investigator working with the select agent or toxin. Based on the data obtained from the 264 entities registered with CDC (this number excludes registered federal government entities), there are approximately 2 principal investigators for each registered entity. For new applications submitted to the CDC since the last submission, CDC estimates based on the information obtained from the database that 5 applications will be submitted from entities wishing to register with CDC to possess, use or transfer select agents and toxins on an annual basis. We have used these figures to calculate the burden for this section. Estimated burden for the Application for Registration is 375 hours.

Entities may amend their registration (42 CFR, 73.7(h)(1)) if any changes occur in the information submitted to CDC. To apply 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 CDC. Estimated time to amend a registration package is 1 hour. Based on the data regarding amendments received from registered entities since the last submission, CDC estimates 5 amendment request to entity's certificate of registration will be received on an annual basis.

The Request to Transfer Select Agent or Toxin form (42 CFR 73.16) will be used by entities requesting transfer of a select agent or toxin to their facility. CDC in conjunction with APHIS has revised the Request to Transfer Select Agent or Toxin form by requiring the recipient to submit the initial request, be notified by the sender of the expected shipment date, and verify if the shipment did not occur. Estimated average time to complete this form is 1 hour, 30 minutes. Based on data regarding the transfer requests received since the last submission, CDC estimates 4 transfer requests submitted per registered entity on an annual basis.

The Report of Theft, Loss, or Release of Select Agent and Toxin form (42 CFR 73.19(a)(b)) must be completed by entities whenever there is theft, loss, or release of a select agent or toxin. Estimated average time to complete this form is 1 hour. Based on data regarding the reports received since the last submission, CDC estimates that 60 reports per respondent will be received on an annual basis.

The Report of Identification of Select Agent or Toxin form (42 CFR 73.5(a)(b) and 73.6(a)(b)) will be used by clinical and diagnostic laboratories to notify CDC that select agents or toxins identified as the result of diagnostic or proficiency testing have been disposed of in a proper manner. In addition, the form will be used by Federal law enforcement agencies to report the seizure and final disposition of select agents and toxins. CDC in conjunction with APHIS has revised the Report of Identification of Select Agent or Toxin form to ensure duplicate reports are not submitted by requesting the entity that makes the final identification report the select agents or toxins identified as the result of diagnostic or verification testing. Estimated average time to complete this form is 1 hour. Based on data regarding the reports received since the last submission, CDC estimates that 10 reports per respondent will be received on an annual basis.

The Request for Exemption form (42 CFR 73.5 (d)(e) and 73.6 (d)(e)) will be used by entities that are using an investigational product that are, bear, or contain select agents or toxins or in

cases of public health emergency. Estimated average time to complete this form is 1 hour. Based on data regarding the requests received since the last submission, CDC estimates that 5 requests per respondent will be received on an annual basis.

In addition to the standardized forms, this regulation also outlines situations in which an entity must notify or may make a request of the HHS Secretary in writing. 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. The estimated time to gather the information and submit this request is 30 minutes. CDC has not developed standardized forms to use in the above situations. Rather, the entity should provide the information as requested in the appropriate section of the regulation.

An entity may also apply to the HHS Secretary for an exclusion of an attenuated strain of a select agent or toxin that does not pose a severe threat to public health and safety (42 CFR 73.3(e)(1) and 73.4(e)(1)). The estimated time to gather the information and submit this request is 1 hour.

As part of the requirements of the Responsible Official, the Responsible Official is required to conduct regular inspections (at least annually) of the laboratory where select agents or toxins are stored. Results of these self-inspections must be documented (42 CFR 73.9(a)(5)). CDC estimates, that, on average, such documentation will take 1 hour.

As part of the training requirements of this regulation, the entity is required to record the identity of the individual trained, the date of training, and the means used to verify that the employee understood the training (42 CFR 73.15(c)). Estimated time for this documentation is 2 hours per principal investigator.

An individual or entity may request administrative review of a decision denying or revoking certification of registration or an individual may appeal a denial of access approval (42 CFR 73.20). This request must be made in writing and within 30 calendar days after the adverse decision. This request should include a statement of the factual basis for the review. CDC estimates the time to prepare and submit such a request is 4 hours.

An entity must implement a system to ensure that certain records and databases are accurate and that the authenticity of records may be verified (42 CFR 73.17(b)). The time to implement such a system is estimated to average 4 hours.

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. CDC estimates the time to prepare and submit a response for the inspection is 8 hours. To estimate the burden, we use the total number of registered entities since each entity will be inspected at least once during the course of their registration.

ESTIMATED ANNUALIZED BURDEN HOURS

CFR reference	Form	Number of respondents	Responses per respondent	Average burden per response (in hours)	Total annual burden (in hours)
73.7(d)	Registration Application	5	1	5	25
73.7(h)(1)	Amendment to Registration Application	264	5	1	1,320
73.19(a)(b)	Notification of Theft, Loss, or Release form.	60	1	1	60
73.5 & 73.6(d–e)/ 73.3 & 73.4(e)(1).	Request for Exemption/Exclusion	5	1	1	5
73.16	Request to Transfer Select Agent or Toxin.	264	4	2	2,112
73.5 & 73.6(a)(b)	Report of Identification of Select Agent or Toxin form.	264	10	1	2,640
73.10(e)	Request expedited review	10	1	1	10
73.9(a)(5)	Documentation of self-inspection	264	1	1	264
73.15(c)	Documentation of training	264	1	2	528
73.20	Administrative Review	15	1	4	60
73.17	Ensure secure recordkeeping system	264	1	4	1,056
73.18	Inspections	264	1	8	2,112
Total					9,657

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