BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-20-0572; Docket No. CDC-2020-0034]

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 the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73). This information collection intends to support the Public Health Safety and Bioterrorism Preparedness and

Response Act of 2002 and ensure select agents or toxins are managed appropriately to prevent any threats to human health or safety. Data will be used to fulfill the requirements promulgated by HHS under this part and also subject to corresponding regulations promulgated by USDA.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-20-0034 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, 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. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments 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 Jeffrey M. Zirger, 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.

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 the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. 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 submissions of responses.
5. Assess information collection costs.

Proposed Project

Possession, Use, and Transfer of Select Agents and Toxins (OMB Control No. 0920-0576) – Revision - Center for Preparedness and Response (CPR), 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 agents 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 Notification and Reporting (Theft, Loss, or Release) (APHIS/CDC Form 3); 4) Reporting the Identification of a Select Agent or Toxin (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 the 2018 Annual Report of the Federal Select Agent Program available at https://www.selectagents.gov/annualreport2018.html or FSAP IT system and is estimated as 4465 hours. Information will be collected through FSAP IT system, fax, email and hard copy mail from respondents. Upon OMB approval, CDC will begin use of the revised forms in October 2020 through October 2023. 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
Sections 3 & 4	Request for Exclusions	1	1	1	1
Sections 5 & 6	Report of Identification of a Select Agent or Toxin	1,181	1	1	1,181
Sections 5 & 6	Request of Exemption	1	1	1	1
Section 7	Application for Registration	3	1	5	15

Section 7	Amendment to a Certificate of Registration	253	5	1	1,265
Section 9	Documentation of self-inspection	253	1	1	253
Section 10	Request for Expedited Review	1	1	0.5	1
Section 11	Security Plan	253	1	1	253
Section 12	Biosafety Plan	253	1	1	253
Section 13	Request Regarding a Restricted Experiment	1	1	2	2
Section 14	Incident Response Plan	253	1	1	253
Section 15	Training	253	1	1	252
Section 16	Request to Transfer Select Agents and Toxins	253	1	1.5	380
Section 17	Records	253	1	0.5	127
Section 19	Notification of Theft, Loss, or Release	201	1	1	201
Section 20	Administrative Review	28	1	1	28
Total					4465

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[FR Doc. 2020-06948 Filed: 4/2/2020 8:45 am; Publication Date: 4/3/2020]