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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-23-0576; Docket No. CDC-2023-0061]

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. This data collection allows CDC to continue to collect information and ensure compliance under the Select Agent regulations.

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

ADDRESSES: You may submit comments, identified by Docket No. CDC-2023-0061 by either of the following methods:

- Federal eRulemaking Portal: www.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, NE, MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to www.regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (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 Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 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;
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; and

5. Assess information collection costs.

Proposed Project

Possession, Use, and Transfer of Select Agents and Toxins (42 CFR 73) (OMB Control No. 0920-0576, Exp. 1/31/2024) - Extension - Office of Readiness and Response (ORR), 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 Division of Agricultural Select Agents and Toxins (DASAT) to administer the select agent regulations in a manner to minimize the administrative burden on persons subject to the select agent regulations. 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:

- Application for Registration for Possession. Use, and Transfer of Select Agents and Toxins (APHIS/CDC Form 1) with an addendum form: Form 1 Sec 6A - Amendment to a Certificate of Registration
- Request to Transfer Select Agents or Toxins (APHIS/CDC Form 2)
- Incident Notification and Reporting (Theft, Loss, or Release) (APHIS/CDC Form 3)
- Reporting the Identification of a Select Agent or Toxin (APHIS/CDC Form 4)
- Request for Exemption of Select Agents and Toxins for an Investigational Product (APHIS/CDC Form 5).

In addition to the forms listed above, the following forms will also be used:

- Request for Exclusions - 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)).
- Documentation of self-inspection - Annual inspections that are conducted by the entity must be documented. (42 CFR 73.9(a)(6)).
- Request for Expedited Review - 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)).
- Request Regarding a Restricted Experiment - An individual or entity may request approval to perform a "restricted experiment" (42 CFR 73.13).
- Security Plan - 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)).

- Training - 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)).
- Administrative Review - An individual or entity may appeal a denial, revocation, or suspension of registration. (42 CFR 73.20(a)).
- Biosafety Plan - An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent (42 CFR 73.12(a)).
- Incident Response Plan - An individual or entity required to register under this part must develop and implement a written incident response plan based upon a site specific risk assessment. The incident response plan must be coordinated with any entity-wide plans, kept in the workplace, and available to employees for review (42 CFR 73.14 (a)).
- Records - An individual or entity required to register under this part must maintain complete records relating to the activities covered by the select agent regulations (42 CFR 73.17 (a)).

The total estimated annualized burden for all data collection was calculated using the 2021 Annual Report of the Federal Select Agent Program available at https://www.selectagents.gov/resources/publications/annualreport/2021.htm or FSAP IT system and is estimated as 3,539 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 January 2024 through January 2027. There is no cost to the respondents.

Estimated Annualized Burden Hours

Section	Form Name	Number of	Number of	Average	Total

		Respondents	Responses per Respondent	Burden per Response (in hours)	Burden Hours
Sections 3 & 4	Request for Exclusions	1	1	1	1
Sections 5 & 6	Form 4 - Report of Identification of a Select Agent or Toxin	917	1	1	917
Sections 5 & 6	Form 5 - Request of Exemption	1	1	1	1
Section 7	Form 1 - Application for Registration	5	1	5	25
Section 7	Form 1 Sec 6A - Amendment to a Certificate of Registration	144	5	1	720
Section 9	Documentation of self-inspection	233	1	1	233
Section 10	Request for Expedited Review	1	1	30/60	1
Section 11	Security Plan	233	1	1	233
Section 12	Biosafety Plan	233	1	1	233
Section 13	Request Regarding a Restricted Experiment	3	1	2	6
Section 14	Incident Response Plan	233	1	1	233
Section 15	Training	233	1	1	233
Section 16	Form 2 - Request to Transfer Select Agents and Toxins	229	1	1.5	380
Section 17	Records	233	1	30/60	117
Section 19	Form 3 - Notification of Theft, Loss, or Release	185	1	1	185
Section 20	Administrative Review	22	1	1	22
Total					3539

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