



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-26-0576; Docket No. CDC-2026-1486]

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 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 73). This data collection allows CDC and APHIS have to collect information on the possession, use, and transfer of select agents and toxins.

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-2026-1486 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. 2/28/2027) - Revision - 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. Accordingly, CDC

and APHIS have adopted an identical system to collect information for the possession, use, and transfer of select agents and toxins.

Since the implementation of the select agent and toxin regulations in 2003 (HHS/CDC, 2003), unless a regulatory exemption or exclusion is applied, individuals and entities are required to register with HHS or USDA to possess a select agent or toxin. Possession of regulated material without proper registration is a regulatory violation that could result in civil, criminal, and/or administrative penalties. Since this time, there have been at least 100 instances of reports from entities that “discovered” a select agent or toxin in their possession that the individual or entity was not registered to possess as required. Many of the agents and toxins “discovered” were from studies associated with personnel who had left their entity, and the custodianship of samples was not reassigned. Some of the materials were labeled with obsolete pathogen names, while other “discovered” material were found in laboratories where their active use had ceased, in some cases, decades prior to the establishment of the select agent and toxin regulations.

HHS/CDC continues to receive reports from entities who find themselves in possession of select agents and toxins that they are not registered to possess. Given these instances, HHS/CDC is proposing to amend section 73.2 of the regulations to clearly state that any individual or entity in possession of a select agent or toxin, for which (1) an exclusion or exemption listed in 42 CFR part 73 does not apply, and (2) that is not included on a certificate of registration issued by the HHS Secretary or USDA Administrator for that individual or entity, must immediately report such possession to either the HHS Secretary or USDA Administrator. This proposal ensures that all discoveries of possession of a select agent or toxin is reported using the proposed new form regardless of if the individual or entity is registered with the program. As such, registered entities that knowingly come into possession of a material prior to amending their registration would report the possession using the proposed form. HHS/CDC would be interested in comments regarding the proposal to ensure the reporting of discovered select agents and toxins including if there is an undue burden being placed on registered entities

to report the discovery as well as amending their registration. To facilitate such reporting, HHS and USDA proposes, in compliance with the Paperwork Reduction Act, a new APHIS/CDC form, Report of Discovery of Select Agent or Toxin form (42 CFR 73.19(c) (Form 6), to specify the information that must be submitted regarding the discovery of the select agent or toxin. Establishing a standard form for reporting will enable HHS and USDA to better understand the circumstances and assess regulatory violations related to the possession of “discovered” select agents and toxins.

CDC is requesting OMB approval to revise this existing information collection to continue to collect information under the select agent regulations through the use of five approved forms and to add a sixth form:

- 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)
- Report of Discovery of Select Agent or Toxin form (42 CFR 73.19(c) (APHIS/CDC Form 6).

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)).
- Report of Discovery of Select Agent or Toxin form (42 CFR 73.19(c) (Form 6) – This is a new form that will be completed by entities whenever there is discovery of a select agent or toxin. Previously, a discovery of a select agent or toxin had to be reported using Form 3, which was not specifically created to report discoveries. The new Form 6 would replace Form 3 in this process.

The total estimated annualized burden for all data collection is estimated as 8,919 hours. This is an increase of 5,416 burden hours from the previous approval due to : (1) changes in the number of respondents; (2) shifts in the average burden per response (measured in hours) across the various forms; (3) the introduction of Form 6 to capture discoveries of a select agent or toxin previously reported via Form 3; and (4) minor corrections to burden estimates in the previously approved 2023 OMB submission, which had underestimated the average burden per response as described in Notice of Proposed Rulemaking published 1/30/2024

<https://www.federalregister.gov/documents/2024/01/30/2024-01513/possession-use-and-transfer-of-select-agents-and-toxins-biennial-review-of-the-list-of-select-agents>. Information will be collected through FSAP IT system, fax, email and hard copy mail from respondents. CDC requests a three-year approval for this information collection request. There is no cost to the 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)	Total Burden Hours
Sections 3	Request for Exclusions	1	1	1	1

& 4					
Sections 5 & 6	Form 4 - Report of Identification of a Select Agent or Toxin	1484	1	1	1484
Sections 5 & 6	Form 5 - Request of Exemption	1	1	0.5	1
Section 7	Form 1 - Application for Registration	3	1	31	93
Section 1-7	Form 1 - Amendment to a Certificate of Registration	960	1	4	3840
Section 9	Documentation of self-inspection	230	1	1	230
Section 10	Request for Expedited Review	15	1	0.5	8
Section 11	Security Plan	230	1	1	230
Section 12	Biosafety Plan	230	1	1	230
Section 13	Request Regarding a Restricted Experiment	2	1	2	4
Section 14	Incident Response Plan	230	1	1	230
Section 15	Training	230	1	8	1840
Section 16	Form 2 - Request to Transfer Select Agents and Toxins	231	1	1.5	347
Section 17	Records	230	1	0.5	115
Section 19	Form 3 - Notification of Theft, Loss, or Release	262	1	1	262
Section 20	Administrative Review	1	1	1	1
Section 20	Form 6 - Report of Discovery of Select Agent or Toxin form 42 CFR 73.19(c)	20	1	10/60	3
Total					8,919

Jeffrey M. Zirger,

Lead,

Information Collection Review Office,

Office of Public Health Ethics and Regulations,

Office of Science,

Centers for Disease Control and Prevention.

[FR Doc. 2026-18217 Filed: 9/4/2026 8:45 am; Publication Date: 9/8/2026]