

Request for Non-substantive Change to an OMB-Approved Information Collection

Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73)
(OMB Control No. 0920-0576) Expiration 10/31/2020

Centers for Disease Control and Prevention
Office of Public Health Preparedness and Response
Division of Select Agents and Toxins

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Request for Non-substantive Change to an OMB-Approved Information Collection

Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73) (OMB Control No. 0920-0576) Expiration 10/31/2020

Justification for Change

As indicated in the attached screen prints (Attachment 1) and comparison to the forms approved by the Office of Management and Budget (OMB) for OMB Control No. 0920-0576 (Expiration date 10/31/2020), there are no changes to the OMB approved information collection for Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73) (OMB Control No. 0920-0576) Expiration 12/31/2018. The “APHIS/CDC Form 5: Request for Exemption of Select Agents and Toxins for an Investigational Product” will not be included in the new system. Applicants will still complete the pdf available on the Federal Select Agent Program website.

This request for nonmaterial/non-substantive changes is to change our database from “National Select Agent Registry (NSAR)” to “Electronic Federal Select Agent Program portal (eFSAP)/Electronic Import Permit Program portal (eIPP).” There are no changes in the data that will be maintained in eFSAP system. The system will still contain records about the select agents or toxins at each facility, the individuals approved for access to these agents and toxins, laboratory biosafety and security information for these agents and toxins, and observations from the inspections of each registered entity. The eFSAP system allows the regulated community to report information or make requests electronically via a single web portal. This process allows the regulated community to interact with the Program more efficiently, allow for better and faster reporting of potential losses, and reduce the program burden and reliance on labor-intensive and paper-based processes. The new system utilizes a secured database environment to provide regulatory responses faster, provide guidance more quickly, and respond rapidly to public health emergencies.

Forms affected by this non-substantive change request:

Application for Registration – Form 1 (Att1) – All information captured by the previously approved form will be captured in eFSAP. No change in data collection or burden.

Request to Transfer - Form 2 (Att2) - All information captured by the previously approved form will be captured in eFSAP. No change in data collection or burden.

Incident and Reporting - Form 3 (Att3) - All information captured by the previously approved form will be captured in eFSAP. No change in data collection or burden.

Reporting the Identification of Select Agent from Form from Clinical Specimens – Form 4A (Att4a)
- All information captured by the previously approved form will be captured in eFSAP. No change in data

collection or burden.

Reporting the Identification of Select Agent from Proficiency Test - Form 4B (Att4b) - All information captured by the previously approved form will be captured in eFSAP. No change in data collection or burden.

Reporting the Identification of Select Agent from Federal Law Enforcement Seizure - Form 4C (Att4c) - All information captured by the previously approved form will be captured in eFSAP. No change in data collection or burden.

Form	Current method of respondent data collection	Requested change for data collection
Application for Registration – Form 1	Electronic Form	Direct input into eFSAP
Request to Transfer - Form 2	Electronic Form	Direct input into eFSAP
Incident and Reporting - Form 3	Electronic Form	Direct input into eFSAP
Reporting the Identification of Select Agent from Form from Clinical Specimens – Form 4A	Electronic Form	Direct input into eFSAP
Reporting the Identification of Select Agent from Proficiency Test - Form 4B	Electronic Form	Direct input into eFSAP
Reporting the Identification of Select Agent from Federal Law Enforcement Seizure - Form 4C (Att4c)	Electronic Form	Direct input into eFSAP

Since there are no changes to the form or the data being collected, this request will not affect the burden in completing the forms. To comply with OMB Memoranda (M) 07-16, Safeguarding Against and Responding to the Breach of Personally Identifiable Information, a Federal Register notice Vol. 76, No. 16, Tuesday, January 25, 2011 was published to alter the System of Records, 09-20-0170 (Attachment 5), National Select Agent Registry (NSAR)/Select Agent Transfer and Entity Registration Information System (SATERIS), HHS/CDC/COTPER. The System of Records is currently being revised because the information system is being modified from “NSAR” to “Electronic Federal Select Agent Program portal (eFSAP portal)/Electronic Import Permit Program portal (eIPP portal) (Attachment 6).”

