Federal Select Agent Program eFSAP Feedback Survey

Generic Information Collection (0920-1154)

Supporting Statement Part A

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Attachment 2a - eFSAP User Experience Survey Instructions

Attachment 3 – Determination of Applicability of Human Subjects Regulations

- **Goals of the project:** The purpose of this project is to conduct a survey to better understand the regulated entities experience with eFSAP and what improvements are needed with the system.

- **Intended use of the resulting data:** Results of this information collections will inform the development of IT tools to determine what improvements are needed with eFSAP.

- **Methods to be used to collect data: S**urveys will be emailed to participants to collect information

- **The subpopulation to be studied:** Registered entities with the Federal Select Agent Program will be asked to respond to this information collection.

- **How data will be analyzed:** Responses to survey will be analyzed regarding what improvements are needed to eFSAP.

1. Circumstances Making the Collection of Information Necessary

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 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, the Department of Health and Human Services (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 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 agent 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. eFSAP is the secured information used by FSAP to submit select agent program information through an electronic portal. This two-way portal is accessible by both FSAP and the regulated community.

The Centers for Disease Control and Prevention (CDC) is requesting approval for a new generic information collection (gen-IC), "Federal Select Agent Program eFSAP Feedback Survey." The goal of this information gathering survey is to better understand the regulated entities and their experience with eFSAP.. This information collected from respondents will allow CDC to build upon its existing tools used to regulate select agents used in registered facilities.

2. Purpose and Use of Information Collection

The purpose of this project is to conduct a theory driven formative evaluation to examine the responses to surveys to determine if improvements are needed for eFSAP. Allowing registered facilities to provide information about their facilities, their systems and their user experience to CDC will help the agency improve the eFSAP system to ensure that it will address the specific needs of the regulated entities as well as improve the relationship between regulated entities and CDC.

3. Use of Improved Information Technology and Burden Reduction

Data will be collected via two separate email surveys to Responsible Officials of registered entities to collect information about. The first survey **eFSAP System Enhancement Survey** (**Attachment 1**) will collect information about their facilities, personnel and records management systems. Instructions will be provided with the **eFSAP System Enhancement Survey** (Attachment 1a). The second survey **eFSAP User Experience Survey (Attachment 2)** will collect information about respondents experience with eFSAP. Instructions will be provided with **eFSAP User Experience Survey (Attachment 2a)**.

4. Efforts to Identify Duplication and Use of Similar Information

The Public Health Safety and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107) required the development of a common registration system. There is no similar database available to identify individuals or entities registered to possess, use and transfer select agents and toxins.

5. Impact on Small Businesses or Other Small Entities

CDC recognizes that a small number of entities affected by the data collection requirements of this regulation may be small businesses. For this reason, the information needed in the data collection has been kept to a minimum.

6. Consequences of Collecting the Information Less Frequently

There are legal obstacles to reducing the burden by collecting this information less frequently.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances with this information collection package. This request fully complies with the guidelines in 5 CFR 1320.5 and will be voluntary.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. This information collection request does not require publication of a 60-day notice in the *Federal Register*.

B. This request does not involve consultation outside the agency.

9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive any payment or gift.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The Division of Select Agents and Toxins (DSAT) has determined that the Privacy Act does not apply to this information collection.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

Institutional Review Board (IRB)

This project was reviewed by DSAT determined to not meet the definition of research under 45 CFR 46. IRB review is not required (Attachment 3).

Justification for Sensitive Questions
There are no sensitive questions in this data collection.

12. Estimates of Annualized Burden Hours and Costs
Table 1 below describes the burden associated with the information collection.
The burden estimate includes the burden to review information. The total estimated burden is 88 hours.

Table 1. Annualized Burden

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden Per Response (hours)	Total Burden Hours
Registered Entity	eFSAP System Enhancement Survey	264	1	10/60	44
Registered Entity	eFSAP User Experience Survey	264	1	10/60	44
Total					88

Table 2 below describes the cost burden associated with this information collection. It was calculated based on the hourly wage rate for "all occupations" in the Bureau of Labor Statistics May 2017 National Occupational Employment and Wage Estimates (BLS, 2017) and from the U.S. Department of Labor Federal Minimum Wage Standards.

Table 2. Cost burden associated with information collection

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Registered Entity	eFSAP System Enhancement Survey	44	$42.45	$ 1867.80
Registered Entity	eFSAP User Experience Survey	44	$42.45	$1867.80
Total				$ 3735.60

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers
There will be no direct costs to the respondents other than their time to participate in the information collection.

14. Annualized Cost to the Government
The estimated annual cost to the Federal government is $42.45 using the pay scale of GS-13 compiling the data in two hours. The basis of the estimate was obtained from the GS-13 who performs a similar task of compiling the data from the electronic survey tool.

Table 3.

		Total ($)
Federal Government Personnel Costs	CDC Microbiologist (GS-13)	$ 84.90
Total		$ 84.90

15. Explanation for Program Changes or Adjustments
This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule
There are no plans for tabulation and publication of these data.

17. Reason(s) Display of OMB Expiration Date is Inappropriate
The expiration date of OMB approval will be displayed on all information collection instruments.

18. Exceptions to the Certification for Paperwork Reduction Act Submissions
There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.