eFSAP Information System (eFSAP)

December 2024 Updates





Science Module









Science Module

- Entities will use eFSAP to interact with the FSAP Science Office
- Users can submit various request types, respond to requests for information, and track the progress of requests
- Users will be informed of Science Office decisions through eFSAP and will be provided signed decision memos







Science Module (Accessing the Science Module)

 Users will access the Science Module through a link in the navigation ribbon on their landing page



Federal Select Agent Program Information System



♦ Sign Out

Home

Form 2 Form 3 Form 4

Inspections

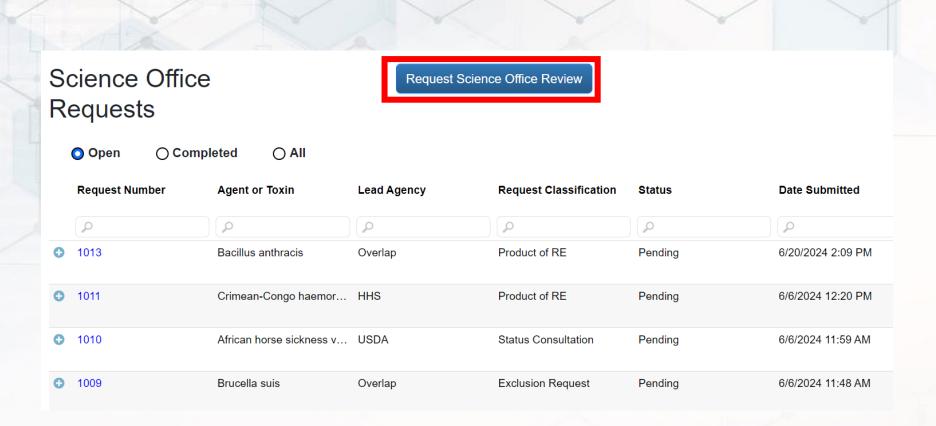
Science Office Request

Admin Center



Science Module (Science Office Request Grid Table)

 From their grid table, users create new Science requests and see, open, or review all previous requests





Science Module (Create Science Office Request)

 When creating a new request, users select from 1 of 7 options and write their cover letter

Home

Request Science Office Review

Select the single item that applies:

- O Restricted Experiment
- Product of Restricted Experiment
- O Select Agent and Toxin Exclusion Request
- O Select Agent and Toxin Status Consultation
- O Select Agent Inactivation Consultation
- O Reconstructed 1918 Influenza Request
- Other

Provide a cover letter for the request for Science Office Review:

We would like to request permission to possess a product resulting from a restricted experiment.



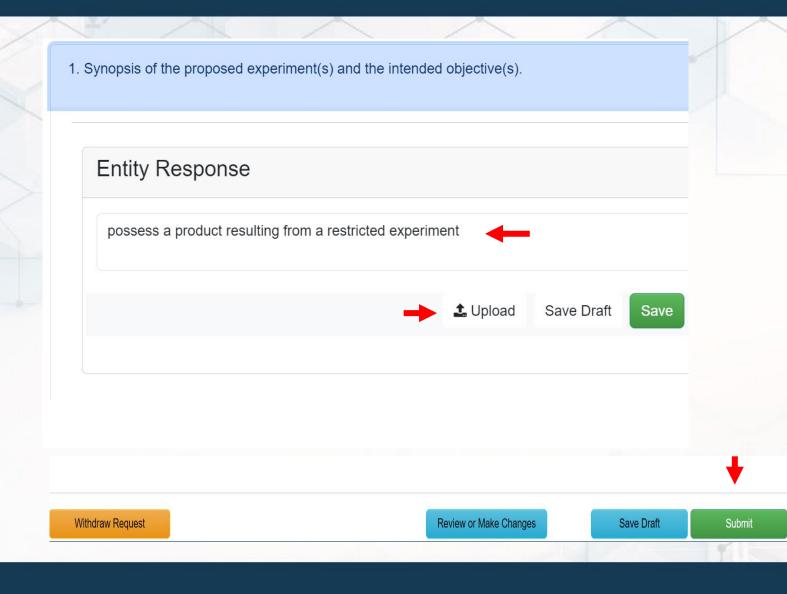






Science Module (Create Science Office Request - Continued)

 Just like amendments, users complete questions specific to the type of request chosen, upload supporting documentation, and submit the request







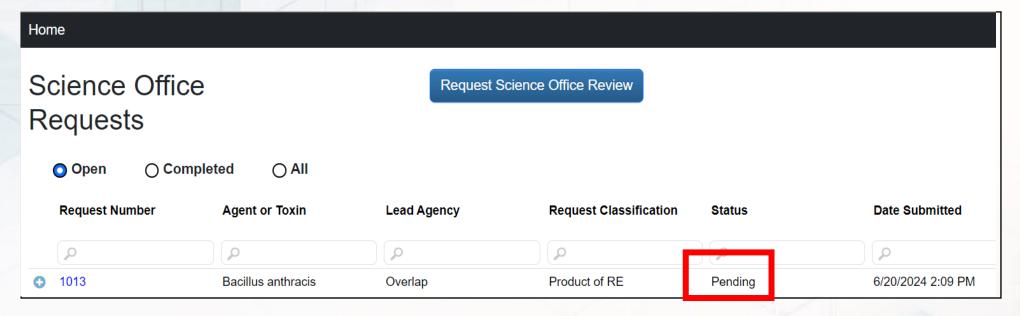






Science Module (Monitoring the Status of Submitted Requests)

 Users monitor the status of the request from the grid table











Science Module (Decision Memo)

 Users are informed of Science Office decisions through eFSAP with an official decision letter that is uploaded to the entity's document library



Department of Health and Human Services U.S. Department of Agriculture Division of Regulatory Science and Atlanta, GA

Centers for Disease Control and Prevention Animal and Plant Health Inspection Service Division of Agriculture Select Agents and Toxins Riverdale, MD



RO Name: #BLANK#

eFSAP Test Entity 1020 Valley Drive Atlanta IN 303291235

RE: Request for Review of Restricted Experiment, 42 C.F.R. 73

Dear #BLANK#,

This letter is the response to your request for review of restricted experiments involving select agent dated August 13, 2024. The experiments involve:

Using the established MUNANA assay to determine if a R292K substitution in H5N1 viruses significantly reduces susceptibility to three licenced NAIs; oseltamivir, zanamivir and peramivir.

in Avian influenza virus performed by Principal Investigator(s). The following aspects of the work are approved or not approved as indicated below. Please ensure adherence to any qualifying conditions as stated.

RE 13(a)(3) is Denied.

The following stipulations apply:

#BLANK#

The approval to conduct restricted experiments and/or possession of the products resulting from the restricted experiments, is limited to at eFSAP Test Entity. If you would like to transfer the product resulting from the restricted experiment to another entity or principal investigator, the receiving entity investigator must submit a written request to the FSAP prior to transfer or possession[Section 13(c)]

Daniel A. Singer, MD, MPH, FACP Acting Director Division of Regulatory Science and Compliance Office of Readiness and Response U.S. Centers for Disease Control and Prevention

Jacek Taniewski, DVM Division of Agricultural Select Agents and Toxins Animal and Plant Health Inspection Service United States Department of Agriculture







