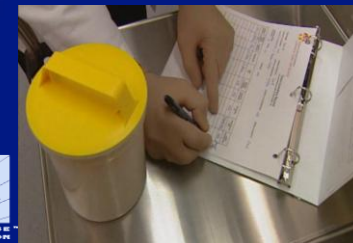


Regulatory Update, and RO role in Approving Access to BSAT



Michael J. Firko, Ph.D.

Director, Agricultural Select Agent Program, APHIS-PPQ

Select Agent Workshop
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Centers for Disease Control and Prevention & Animal and Plant Health Inspection Service
Select Agent Program



Regulatory Update

❑ Advance Notice of Proposed Rulemaking (ANPR)

- ❑ Published July 29, 2010
- ❑ Asked for comments on list and tiering of list, 30-day comment period
- ❑ Comments received: 97

❑ Proposed Rule

- ❑ Plan to publish October 2011
- ❑ 60-day comment period
- ❑ Existing regulations enforced until Final Rule published and implemented

❑ Final Rule

- ❑ Plan to publish October 2012
- ❑ Implementation period

Approval Process for Authorizing Access to BSAT

1. Responsible Official (RO) vets each person requesting access to BSAT at his/her registered entity
2. FBI Form 961 submitted to FBI for each person
3. FBI performs Security Risk Assessment (SRA) and transmits results to APHIS or CDC
4. APHIS or CDC approve access, or not

RO's Are In The Best Position to Control Access to BSAT

- ❑ The RO is on site and has employment control
- ❑ Before an employee completes the Security Risk Assessment (SRA), the RO has complete discretion to evaluate suitability for access to BSAT, using whatever legal tools exist
 - ❑ Significant variation among RO's
- ❑ When CDC and APHIS receive a request, we assume the RO has “vetted” the person with respect to their suitability to access BSAT

FBI Form 961

Consent

Section III:

- By signing this form, I hereby authorize the U.S. Department of Justice to obtain any information relevant to assessing my suitability to access, possess, use, receive or transfer select agents and toxins from any relevant source, including, but not limited to, individuals, public sources, and government sources. This information may include, but is not limited to, biographical, financial, law enforcement and intelligence information.
- I further authorize any individuals having information pertinent to such an assessment to release such information to a duly accredited representative of the U.S. Department of Justice. The authorization set forth in this paragraph is valid for five (5) years from the date on which this form is signed.
- I further authorize the U.S. Department of Justice to disclose any records, results or information relating to, or obtained in connection with, my security risk assessment to: the U.S. Department of Agriculture; the Department of Health and Human Services; any agency contractors assisting in the determination of risk; and responsible officers or other appropriate personnel of pertinent entities.
- I further authorize the release of records, results or information relating to, or obtained in connection with my security risk assessment to any law enforcement or intelligence authority or other federal, state or local entity with relevant jurisdiction where such information reveals a risk to human, animal and/or plant health or national security.
- I further authorize disclosure of records results or information relating to, or obtained in connection with my security risk assessment to organizations or individuals, both public and private, if deemed necessary, in the sole discretion of the U.S. Department of Justice, to elicit information or cooperation from the recipient for use in assessing my suitability to access, possess, use, receive or transfer select agents and toxins.
- I further authorize release of records, results or information relating to, or obtained in connection with my security risk assessment to laboratories, universities, individuals, or other entities, both public and private, responsible for making security assessments, employment and/or licensing determinations and suitability or security decisions when the information is relevant to an assessment of my suitability to access, possess, receive, use, or transfer agents or toxins.
- I understand that this is a legally binding document and false statements provided by me are violations of federal law and may lead to criminal prosecution or other legal action.
- Printed Name:
- Date:
- Signature:

FBI Form 961

Consent

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- I understand that this is a legally binding document and false statements provided by me are violations of federal law and may lead to criminal prosecution or other legal action.
- Printed Name:
- Date:
- Signature:

RO review of FBI 961

- Regarding the assessment to determine suitability to access BSAT...
 - I further authorize any individuals having information pertinent to such an assessment to release such information to a duly accredited representative of the U.S. Department of Justice.

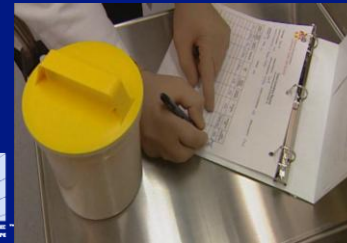
RO review of FBI 961

I further authorize release of [... information...] relating to [...] my security risk assessment to laboratories, universities, individuals, or other entities, both public and private, responsible for making security assessments, employment and/or licensing determinations and suitability or security decisions when the information is relevant to an assessment of my suitability to access, possess, receive, use, or transfer agents or toxins.

The RO controls access

- ❑ The RO has the discretion to remove access at any time
 - ❑ Irrespective of approval from CDC or APHIS
 - ❑ “Passing” the SRA is not a guarantee of access to BSAT

Discussion



For more information, please contact Select Agent Program

Telephone: 301-734-5960 (APHIS) or 404-718-2000 (CDC)

E-mail: Agricultural.Select.Agent.Program@aphis.usda.gov (APHIS) or lrsat@cdc.gov (CDC)

Web: <http://www.selectagent.gov/>

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Select Agent Program.



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