

Select Agents

ChABSA Technical Seminar

March 7, 2024

Overview



The Federal Select Agent Program (**FSAP**) is a joint effort of the **Centers for Disease Control and Prevention (CDC)** and the **Animal and Plant Health Inspection Service (APHIS)**.



It regulates the possession, use, and transfer of **biological select agents and toxins**. 42 CFR 72 (Public Health); 9 CFR 121 (Agriculture); 7 CFR 331 (Animals and Animal Products)



These agents and toxins have the potential to pose a **severe threat** to public, animal, or plant health.

Key Functions of FSAP

Regulation and Oversight:

- Develops, implements, and enforces the **Select Agent Regulations**.
- Ensures compliance with safety and security protocols.
- Conducts inspections of entities handling select agents.

National Database:

- Maintains a comprehensive database of select agents and their handlers.

Security Risk Assessment:

- Requires individuals working with select agents to undergo a **security risk assessment** by the **Federal Bureau of Investigation (FBI)**.

Guidance and Education:

- Provides guidance documents to regulated entities.
- Conducts workshops and webinars to promote compliance.

Incident Investigation:

- Investigates any incidents of non-compliance.

Examples of Select Agents and Toxins

Anthrax (*Bacillus anthracis*)

Botulinum toxin

Ebola virus

Plague bacterium (*Yersinia pestis*)

Ricin toxin

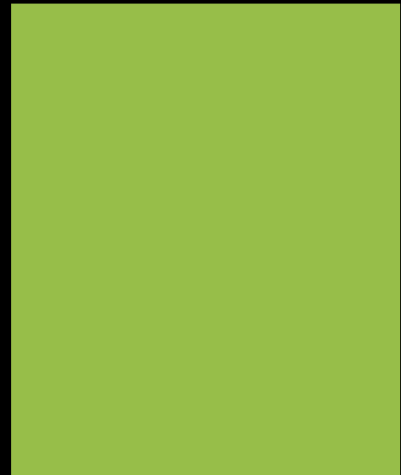
Tularemia bacterium (*Francisella tularensis*)

Conclusion

The FSAP ensures that research involving select agents is conducted safely and securely.

By regulating these materials, it contributes to public health and safety.

THE END.



THE END.

Powered by AI

What Should be in
the RO's Toolbox?

The real reason we are here
tonight...



Disclaimer

- The following is a discussion based on my experiences.
- It is in no way the official position of University of Maryland, Baltimore, or any of my previous employers.
- It is in no way the official position of ABSA International.
- This is me.
- Also, this presentation is rated PG-13. You invited a middle-aged, perimenopausal woman out, gave her a glass of wine, and asked her to talk about Select Agents (trauma). Risk of profanity is moderate. Maybe high.



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Marker



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Marker

- Document everything.
- If it is not written/recorded – it did not happen.
- Dates, times, people, places.
 - Let them know you are taking notes...
 - Share the notes = communicate!
- Separate notebook for you – you may need to reconstruct actions at a much later date.



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Hammer and Screwdriver



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RO/ARO? Regulators? Chair/VP/President? Funding source? IBC/IACUC? Consultant? Lab or Facility Manager? Veterinarian? Facilities?

Hammer and Screwdriver

Support, Authority, Swift and Sure



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Pressure, Applied Consistently



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Hammer and Screwdriver

Regulators. Funding source. IBC/IACUC*. Facilities.
Chair/VP/President. Consultant. Veterinarian.

RO/ARO. Lab/Facility Manager *.



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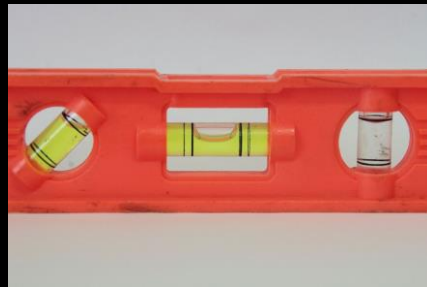


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Measuring Tape and Level



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Measuring Tape and Level



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- Size and shape of the program
- Metrics



- Is everything straight?
- Benchmark, inspections, internal assessments
- Anything that is "off" will draw attention

Saw and Carpet Knife/Razor Blade



Big changes



Precise work

Saw and Carpet Knife/Razor Blade



Staff – additions or cuts/replacements. Reduce/change scope. Reduce/change services. Reduce/change access (staff, time). Modify facilities.



Reassigning duties. Revising protocols. Combine manuals. Aligning IACUC and IBC. Tweak forms for efficiency and better compliance. Modify equipment.

Gift Card



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Gift Card

- Is there a line item for BSAT program?
 - Training – for users and A/ROs
 - Supplies
 - Consultant
- Not always your money you are spending!
 - Facility upgrades and enhancements
 - PPE and equipment
 - Security
 - Staff
 - Refreshments
 - Get your eyes on the grants BEFORE they go in



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Ear Plugs



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Gloves



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Safety Glasses

Ear Plugs

- Ear plugs – drown out the noise
- Gloves – protection (training) so you can get your hands dirty!
- Safety glasses – sometimes it gets messy...



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Gloves



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Safety Glasses

Shovel and Flashlight



Shovel and Flashlight



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Shovel and Flashlight



For digging, not burying!
 Keep digging – uncover, bring to surface
 Dig for proof, references, funding, motivation



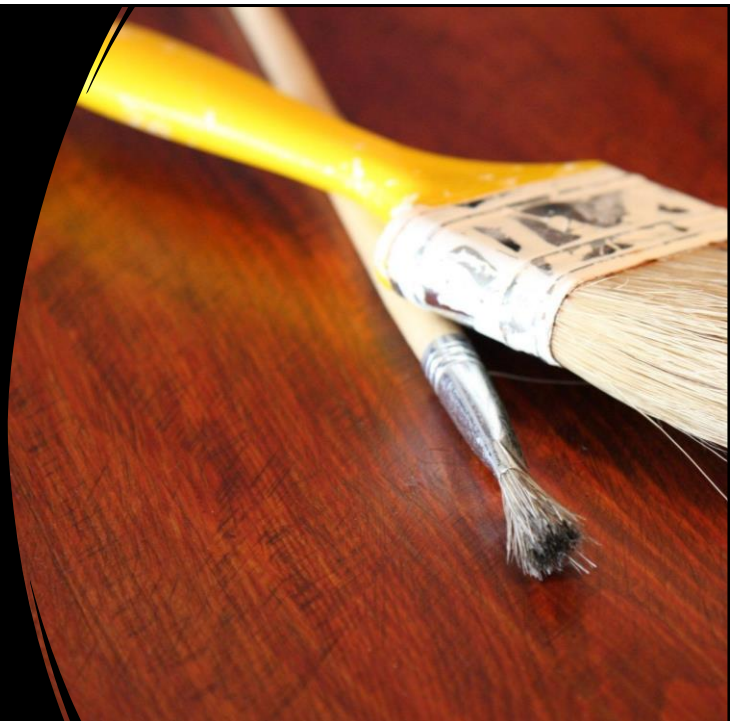
Shine light on every surface!
 Physical – every corner, inside and out, above and under
 Programmatic – inefficiencies, double-standards
 Highlight the good and the not so good!
 Search for solutions!
 Be the light!

Paintbrush



Paintbrush

- Presentable, public facing
- Protective, durable, sealed



Clamps and Tape



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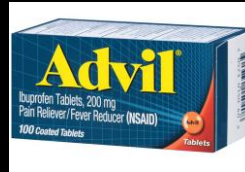
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First Aid Kit



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First Aid Kit



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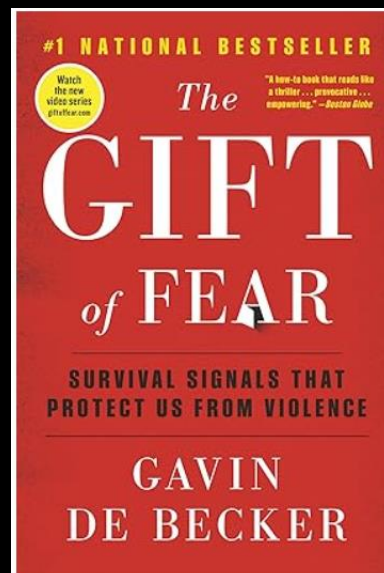
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But what else is in that kit?

- What's your support structure?
- Who are you going to call?
- Who is your "safe" person?
- Do you ever need to "tap out"? What does that look like?
- If you are not ok, it's ok. Get help. Period. Full stop.



YOUR
Experience /
Intuition





(but really, you can... just ask...)

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