

Balancing Security and Transparency for Research Involving Biological Select Agents and Toxins

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HHS National Science Advisory Board for Biosecurity

January 23-24, 2020



U.S. Federal Biosafety & Biosecurity Oversight

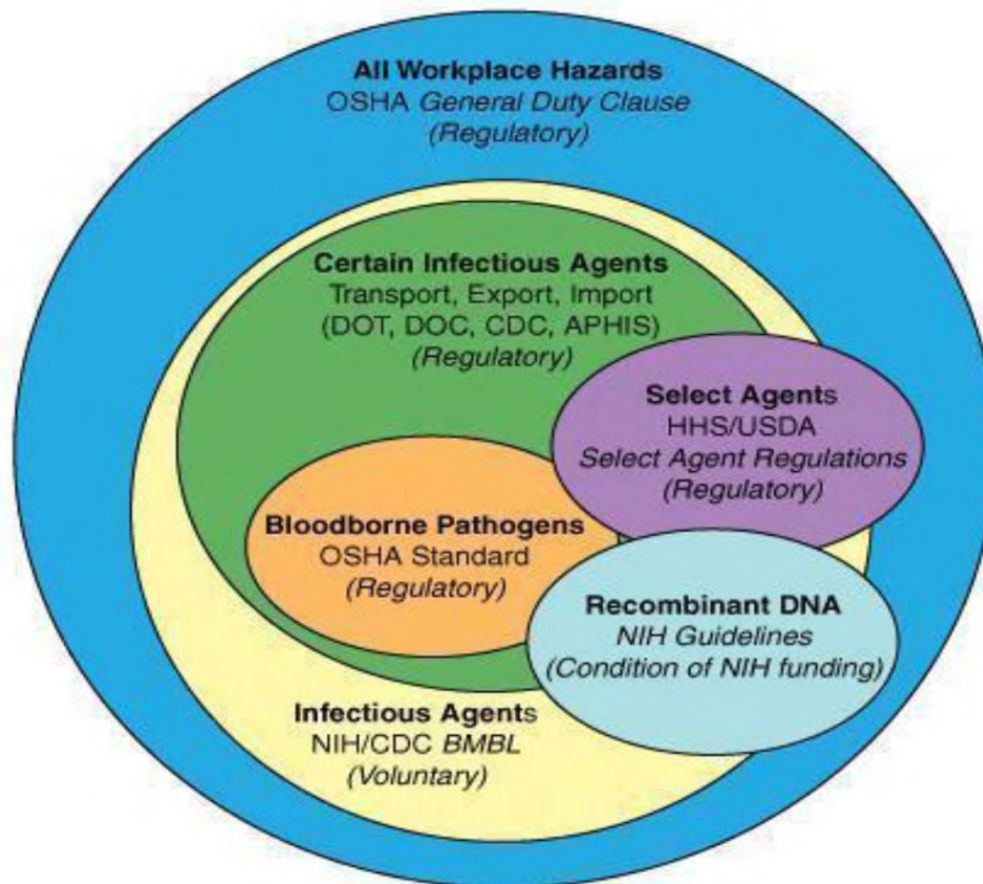
UNITED STATES
DEPARTMENT OF LABOR

OSHA

Occupational Safety & Health Administration



BIOHAZARD



CDC • NIH

5th Edition

Biosafety in Microbiological
and Biomedical Laboratories



CDC



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE



NIH Guidelines for
Research Involving
Recombinant or Synthetic
Nucleic Acid Molecules
(NIH Guidelines)

March 2013



History of the Federal Select Agent Program (FSAP)

Rising Concerns about Bioterrorism in the U.S.

- ❑ **1984 – The Dalles, Oregon**
 - Salmonella/salad bars, 751 infected
 - Religious commune
- ❑ **1992 Minnesota – Deputy Marshal/Sheriff**
 - Ricin-DMSO on office doorknobs
 - Minnesota Patriots Council Militia
- ❑ **1993 Alaska-Canadian border incident**
 - Plastic bag/white powder – Ricin
- ❑ **Oct./Nov. 1996 – Medical Center Lab, Texas**
 - *Shigella dysenteriae*/tainted pastries, 12 infected
 - Probably co-worker



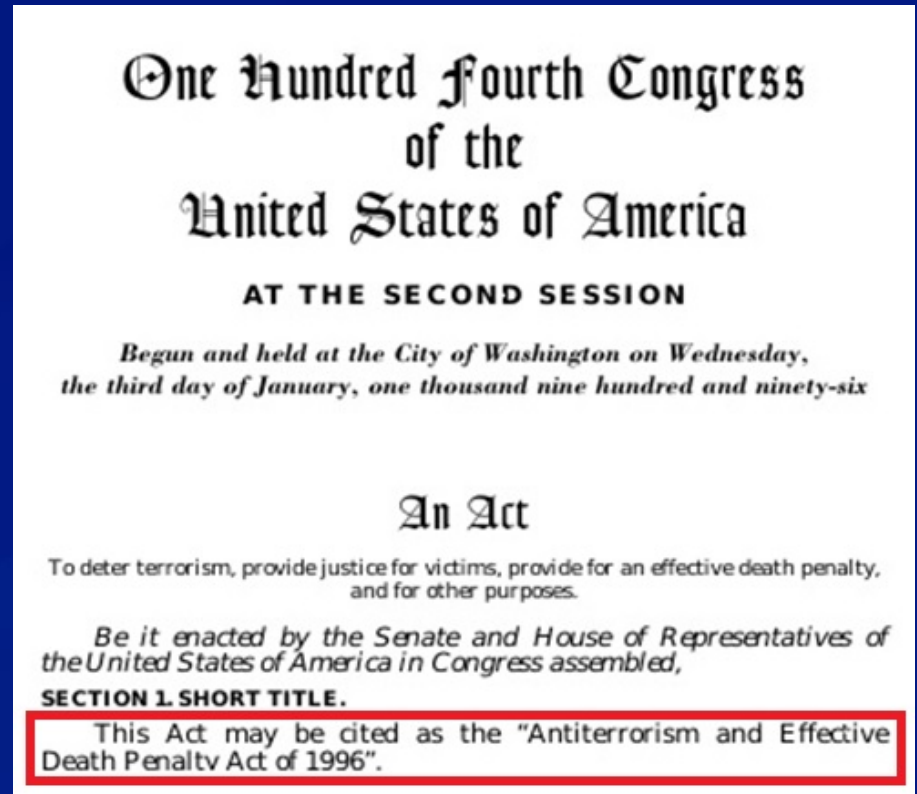
Events Leading to the Select Agent Rule

- ❑ **1993 World Trade Center bombing**
- ❑ **March 20, 1995 – Tokyo subway system**
 - Sarin (12 killed/5,500 injured)
 - Aum Shinrikyo group, also involved in:
 - Ebola virus, Zaire 1992
 - *Clostridium botulinum*, *Bacillus anthracis*, *Coxiella burnetti*
- ❑ **April 1995 – Murrah Federal Building bombing**
- ❑ **May 5, 1995 – Larry Wayne Harris**
 - Ordered *Yersinia pestis*
- ❑ **1995 – Best-seller *Contagion* by Robin Cook**



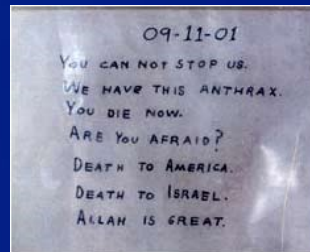
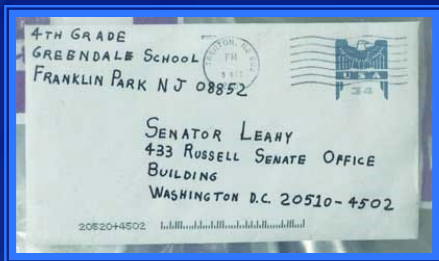
Select Agent Program: Brief Timeline

- ❑ Program created through the Antiterrorism and Effective Death Penalty Act, 1996 (Section 511). HHS was directed to establish:
 - A list of biological agents and toxins that have the potential to threaten public health and safety (select agents)
 - Procedures governing the transfer of those agents
 - Training requirements for entities transferring select agents



Overview & History

- ❑ 2001 anthrax attacks led to strengthening of program
- ❑ Title II of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002
 - Legal authority for the current Federal Select Agent Program
 - Required security measures in addition to biosafety measures
 - Strengthened the regulatory authorities of HHS
 - Granted comparable regulatory authorities to USDA



Title II of The Act: Enhanced Control of Dangerous Biological Select Agents and Toxins

- ❑ **Establish a list of biological select agents and toxins**
 1. Effect of exposure
 2. Degree of contagiousness and method of transmission
 3. Availability of effective pharmacotherapies and immunizations
 4. Other criteria determined to be appropriate by the Secretary
- ❑ **Consult with other federal departments and agencies, as well as scientific experts representing appropriate professional groups**
- ❑ **Review/republish the list biennially, or revise as often as needed**

TITLE II—ENHANCING CONTROLS ON DANGEROUS BIOLOGICAL AGENTS AND TOXINS

“SEC. 351A. ENHANCED CONTROL OF DANGEROUS BIOLOGICAL AGENTS AND TOXINS.

“(a) REGULATORY CONTROL OF CERTAIN BIOLOGICAL AGENTS AND TOXINS.—

“(1) LIST OF BIOLOGICAL AGENTS AND TOXINS.—

“(A) IN GENERAL.—The Secretary shall by regulation establish and maintain a list of each biological agent and each toxin that has the potential to pose a severe threat to public health and safety.

“(B) CRITERIA.—In determining whether to include an agent or toxin on the list under subparagraph (A), the Secretary shall—

“(i) consider—

“(I) the effect on human health of exposure to the agent or toxin;

“(II) the degree of contagiousness of the agent or toxin and the methods by which the agent or toxin is transferred to humans;

“(III) the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin; and

“(IV) any other criteria, including the needs of children and other vulnerable populations, that the Secretary considers appropriate; and

“(ii) consult with appropriate Federal departments and agencies and with scientific experts representing appropriate professional groups, including groups with pediatric expertise.

“(2) BIENNIAL REVIEW.—The Secretary shall review and republish the list under paragraph (1) biennially, or more often as needed, and shall by regulation revise the list as necessary in accordance with such paragraph.

Current Select Agents and Toxins List

HHS and USDA Select Agents and Toxins
7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73

HHS SELECT AGENTS AND TOXINS	OVERLAP SELECT AGENTS AND TOXINS
1. Abrin	36. <i>Bacillus anthracis</i> *
2. <i>Bacillus cereus</i> Biovar <i>anthracis</i> *	37. <i>Bacillus anthracis</i> Pasteur strain
3. Botulinum neurotoxins*	38. <i>Brucella abortus</i>
4. Botulinum neurotoxin producing species of <i>Clostridium</i> *	39. <i>Brucella melitensis</i>
5. Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X ₁ (CCX) ₂ PACGX ₃ X ₄ (S) ₆ (CX) ₇) ¹	40. <i>Brucella suis</i>
6. <i>Coxiella burnetii</i>	41. <i>Burkholderia mallei</i> *
7. Crimean-Congo haemorrhagic fever virus	42. <i>Burkholderia pseudomallei</i> *
8. Diacetoxyscirpenol	43. Hendra virus
9. Eastern Equine Encephalitis virus ³	44. Nipah virus
10. Ebola virus*	45. Rift Valley fever virus
11. <i>Francisella tularensis</i> *	46. Venezuelan equine encephalitis virus ³
12. Lassa fever virus	
13. Lujo virus	USDA SELECT AGENTS AND TOXINS
14. Marburg virus*	47. African horse sickness virus
15. Monkeypox virus ³	48. African swine fever virus
16. Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)	49. Avian influenza virus ³
17. Ricin	50. Classical swine fever virus
18. <i>Rickettsia prowazekii</i>	51. Foot-and-mouth disease virus*
19. SARS-associated coronavirus (SARS-CoV)	52. Goat pox virus
20. Saxitoxin	53. Lumpy skin disease virus
South American Haemorrhagic Fever viruses:	54. <i>Mycoplasma capricolum</i> ³
21. Chapare	55. <i>Mycoplasma mycoides</i> ³
22. Guanarito	56. Newcastle disease virus ^{2,3}
23. Junin	57. Peste des petits ruminants virus
24. Machupo	58. Rinderpest virus*
25. Sabia	59. Sheep pox virus
26. Staphylococcal enterotoxins A,B,C,D,E subtypes	60. Swine vesicular disease virus
27. T-2 toxin	
28. Tetrodotoxin	USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXINS
Tick-borne encephalitis complex (flavi) viruses:	61. <i>Caniothyrium glycinis</i> (formerly <i>Phoma glycinicola</i> and <i>Pyrenochaeta glycinis</i>)
29. Far Eastern subtype	62. <i>Peronosclerospora philippinensis</i> (<i>Peronosclerospora sacchari</i>)
30. Siberian subtype	63. <i>Ralstonia solanacearum</i>
31. Kyasanur Forest disease virus	64. <i>Rathayibacter toxicus</i>
32. Omsk hemorrhagic fever virus	65. <i>Sclerophthora rayssiae</i>
33. Variola major virus (Smallpox virus)*	66. <i>Synchytrium endobioticum</i>
34. Variola minor virus (Alastrim)*	67. <i>Xanthomonas oryzae</i>
35. <i>Yersinia pestis</i> *	

*Denotes Tier 1 Agent

67 Agents and Toxins on the HHS and USDA list:

- 35 HHS only
- 21 USDA only
- 11 Overlap

Including 14 Tier 1 agents

<https://www.selectagents.gov/SelectAgentsandToxinsList.html>

Tier 1 Select Agents and Toxins

- ❑ Tier 1 is a subset of the select agents and toxins list that presents the greatest risk of deliberate misuse with the most significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence

HHS select agents and toxins

- (1) *Bacillus cereus* Biovar *anthracis*
- (2) Botulinum neurotoxin
- (3) Botulinum neurotoxin producing species of *Clostridium*
- (4) Ebola virus
- (5) *Francisella tularensis*
- (6) Marburg virus
- (7) Variola major virus
- (8) Variola minor virus
- (9) *Yersinia pestis*

USDA select agents

- (1) Foot-and-Mouth Disease virus
- (2) Rinderpest virus

Overlap select agents

- (1) *Bacillus anthracis* (excluding Pasteur strain)
- (2) *Burkholderia mallei*
- (3) *Burkholderia pseudomallei*

Federal Select Agent Program (FSAP)

- ❑ **Regulates the possession, use, and transfer of biological select agents and toxins (BSAT) with the potential to pose a severe threat to public, animal or plant health, or to animal or plant products**

- ❑ **Managed jointly by:**



- The Division of Select Agents and Toxins (DSAT), Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services (HHS)



- The Agriculture Select Agent Services (AgSAS), Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA)

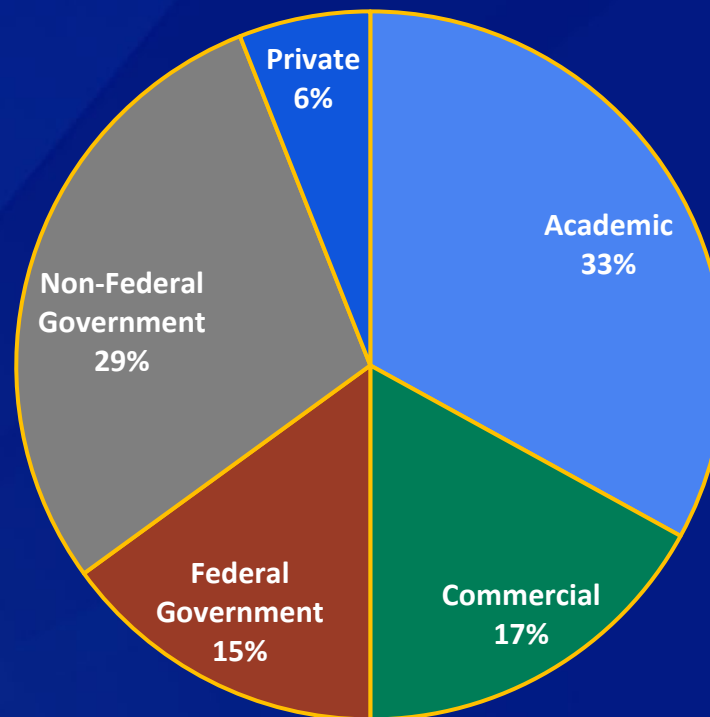
Select Agent Regulations

- ❑ **Relevant regulations include:**
 - 7 C.F.R. Part 331 (plants and plant products)
 - 9 C.F.R. Part 121 (animals and animal products)
 - 42 C.F.R. Part 73 (public health)
- ❑ **List-based regulatory program (currently 67 agents)**
- ❑ **Requires review and republication of agent list every two years**



Types of Entities Registered with FSAP, 2018

Total: 253



Source: 2018 Annual Report of the Federal Select Agent Program, <https://www.selectagents.gov/annualreport2018.html>

Key Regulatory Functions and Activities

- ❑ Promulgate the select agent regulations
- ❑ Provide oversight of possession, use, and transfer
- ❑ Conduct inspections and approve registrations
- ❑ Approve individual access to select agents and toxins
- ❑ Receive reports of a theft, loss, or release
- ❑ Take appropriate enforcement actions
- ❑ Serve as a resource on compliance with the regulations



Inspection Process

- ❑ Inspections may be conducted by FSAP without prior notification and prior to issuing a certificate of registration
- ❑ May include (not all inclusive) evaluation of:
 - Registered laboratories
 - Follow entity entry and exit requirements [personal protective equipment (PPE)]
 - Biosafety (medical surveillance program/plan)
 - Inventory audit/review of inventory records
 - Select agent decontamination policies and procedures
 - Shipping/receiving
 - Transfer procedures/standard operating procedures (SOPs)
 - Division 6.1 and 6.2 training records

Inspection Process

□ Document review

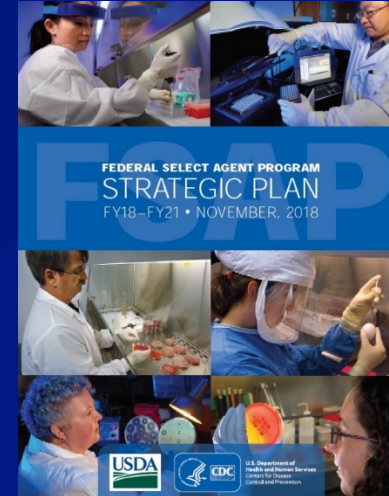
- Plans (biosafety, incident response, security)
- Training
- Access records (manual and electronic, if applicable)
- Institutional Biosafety Committee minutes/approvals
- Institutional Animal Care and Use Committee minutes/approvals
- APHIS/CDC Forms 2, 3, and 4; intra-entity transfers
- Incident reports
- Exercises and after action reports (AAR)

□ Security

- Record observations from time on campus
- Vulnerability assessment reviews, if available
- Visit camera monitoring stations, etc., if applicable

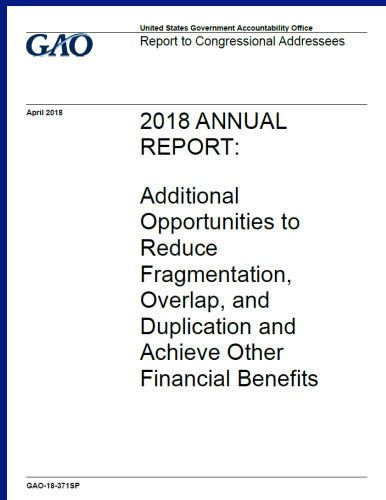
Needs for Transformational Change

- ❑ Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requirement to maintain database
- ❑ GAO's recommendation to improve coordination and oversight
- ❑ National Biodefense Strategy – 2018
- ❑ FSAP Strategic Plan developed covering multiple aspects of the program – focus on system as force multiplier making it possible



FSAP Strategic Plan

1. Ensure the recruitment, development, and retention of a knowledgeable and professional FSAP workforce
2. Harmonize FSAP organizational processes and inspections
3. Leverage data-driven, risk-based approaches to guide FSAP operations
4. Engage, increase transparency, and highlight program benefits, with FSAP's diverse stakeholders



Electronic FSAP (eFSAP) Information System

- ❑ Secure, web-based user interface (portal)
- ❑ Searchable; will provide immediate, real-time information on who has what select agents, how they are being used in the work, and where they are located
- ❑ Increased efficiency; FSAP can be more timely and effective
- ❑ FSAP and regulated entities will both use the set of data
- ❑ Reduced paper
- ❑ New method of releasing inspection findings can help entities work towards resolution in days vs. weeks or months

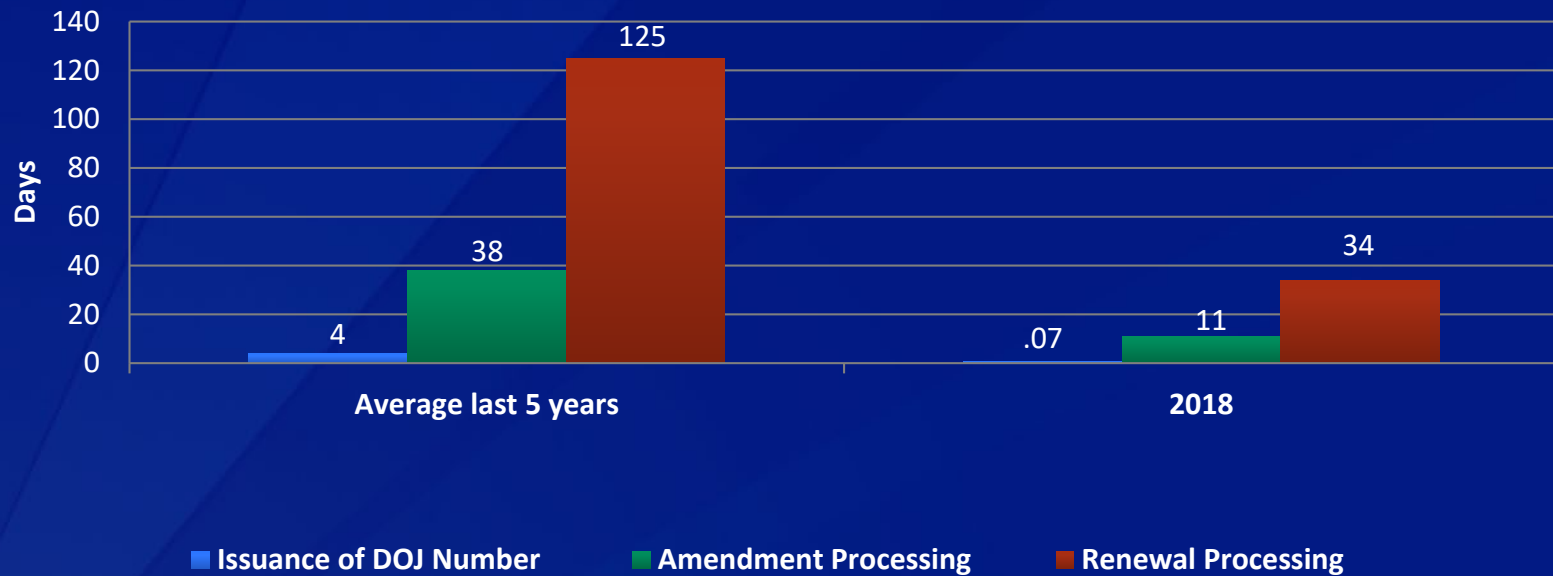
The screenshot displays the 'Federal Select Agent Program Portal' for an 'eFSAP Test Entity'. The page includes logos for CDC and USDA at the top left. A navigation bar contains 'Home' and 'Notifications'. A 'Forms' section lists 'Form 1', 'Form 2', 'Form 3', and 'Form 4'. The main content area shows the following details:

- Entity: eFSAP Test Entity
- LEAD AGENCY: CDC
- REGISTRATION STATUS: Approved
- REGISTRATION EXPIRES: 10/10/2019
- Facility Address: 1020 Valley Drive, Atlanta, GA 303291234
- Responsible Official Name: Stevenson Steve
- Responsible Official Title: Director of Science
- Responsible Official Address: 1020 Valley Drive, Atlanta, GA 30329
- Registration #: 20161010-1852
- Application #: c0c7e336-f01e-e711-80cf-001dd8003fe2
- Type Status: Commercial - Profit

Burden Reduction and Customer Satisfaction

- ❑ **Many aspects of entity registration maintenance have been revamped to be self-service**
 - Reduces administrative burden for both program and entity
 - Significantly speeds up processing
- ❑ **Increased ease of validating and submitting information**
- ❑ **Entities have immediate visibility of where their submissions are in life cycle**
- ❑ **Direct interaction between SMEs and entity representatives**

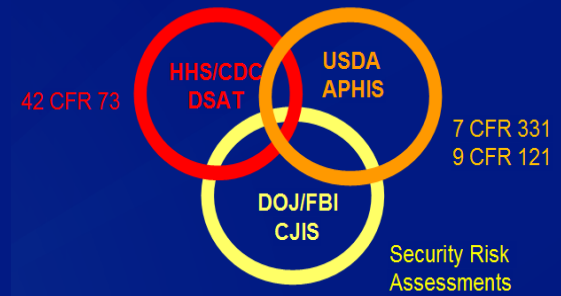
eFSAP Information System: Accelerated Processing Times



Processing times for adding individuals, amendment & renewal processing

Security Risk Assessment (SRA)

- ❑ Required for access to any select agent or toxin
 - Every three years thereafter
- ❑ The FBI, Criminal Justice Information Services Division (CJIS), conducts the SRA
 - Electronic database check based on information and fingerprints
 - Continuous monitoring
 - Restricted persons (18 USC 175b)
- ❑ CJIS sends results to FSAP
- ❑ Based on CJIS determination, FSAP approves or denies access



Who is a “restricted person”?

- ❑ Specified in the USA PATRIOT Act (Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001)
- ❑ No restricted person shall ship, possess, or receive a select agent
- ❑ 18 USC 175b defines “restricted person” as:
 - Under indictment or convicted of crime punishable by imprisonment for a term > 1 year or is a fugitive from justice
 - Unlawful user of any controlled substance
 - Alien illegally or unlawfully in the U.S.
 - Has been adjudicated as a mental defective or has been committed to any mental institution
 - Dishonorable discharge from the Armed Services of the United States
 - Is an alien who is a national of a country that Sec. of State has made a determination has provided support for acts of international terrorism

Select Agent Enforcement

❑ Voluntary action

- Corrective Action Plan (CAP)

❑ Administrative actions

- Denial of application
- Revocation or suspension of registration

❑ Civil money penalties

- Up to \$250k for an individual for each violation
- Up to \$500k for an entity for each violation

❑ Criminal

- Imprisonment for up to 5 years, a fine, or both



Program Metrics

Since 2003, there have been:

- ❑ No reported thefts of a select agent or toxin from a registered entity
- ❑ No deaths among laboratory workers
- ❑ No reported cases of illness or death in the general public due to work with these agents in regulated laboratories



USDA INCIDENT FORM TO REPORT POTENTIAL THEFT, LOSS, RELEASE, OR OCCUPATIONAL EXPOSURE (APHIS/CDC FORM 3)

Animal and Plant Health Inspection Service
Agriculture Select Agent Services
4700 River Road, Unit 2, Manassas, VA 20107
Phone: (801) 774-3022
E-mail: ADAS@aphis.usda.gov

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road, NE, Mailstop 4-05
Atlanta, GA 30333
Phone: (404) 771-9370
E-mail: 2006-0001

Accession Number:
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INSTRUCTIONS
Detailed instructions are available at <http://www.selectagents.gov/Form3.html>. Answer all items completely and type or print in ink. This report must be signed and submitted to either APHIS or CDC.

Submit completed form only once by either email, fax, or mail

SECTION 1 - TO BE COMPLETED BY ALL ENTITIES

1. Date of incident: _____ 2. Date of incident notification: _____ 3. Type of incident notification: _____

4. Name of entity (entity registered with CDC or APHIS) or Name of Hospital or Laboratory (non-registered entities): _____ 5. Entity registered number (for Select Agent registered entities only): _____ 6. Facility registered number (for Select Agent registered entities only): _____

8. Physical Address: _____ 9. City: _____ 10. State: _____ 11. Zip Code: _____

12. Responsible Officer (registered) or Name of Laboratory Supervisor (non-registered): _____ 12a. Fax #: _____ 12b. Email address: _____

14a. Type of incident: Theft Loss Release Unknown Agent Infection Unintentional Point Agent Release Other _____

14b. Type of incident: Theft Loss Release Unknown Agent Infection Unintentional Point Agent Release Other _____

15. Incident description (complete Sections 1 and 2 and Appendix B): _____

16. Type of incident occurred: _____ 17. Location of incident (building and room #): _____ 18. Number of incident (other than 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 209, 210, 211, 212, 213, 214, 215, 216, 217, 218, 219, 220, 221, 222, 223, 224, 225, 226, 227, 228, 229, 230, 231, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, 244, 245, 246, 247, 248, 249, 250, 251, 252, 253, 254, 255, 256, 257, 258, 259, 260, 261, 262, 263, 264, 265, 266, 267, 268, 269, 270, 271, 272, 273, 274, 275, 276, 277, 278, 279, 280, 281, 282, 283, 284, 285, 286, 287, 288, 289, 290, 291, 292, 293, 294, 295, 296, 297, 298, 299, 300, 301, 302, 303, 304, 305, 306, 307, 308, 309, 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 321, 322, 323, 324, 325, 326, 327, 328, 329, 330, 331, 332, 333, 334, 335, 336, 337, 338, 339, 340, 341, 342, 343, 344, 345, 346, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357, 358, 359, 360, 361, 362, 363, 364, 365, 366, 367, 368, 369, 370, 371, 372, 373, 374, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, 397, 398, 399, 400, 401, 402, 403, 404, 405, 406, 407, 408, 409, 410, 411, 412, 413, 414, 415, 416, 417, 418, 419, 420, 421, 422, 423, 424, 425, 426, 427, 428, 429, 430, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 441, 442, 443, 444, 445, 446, 447, 448, 449, 450, 451, 452, 453, 454, 455, 456, 457, 458, 459, 460, 461, 462, 463, 464, 465, 466, 467, 468, 469, 470, 471, 472, 473, 474, 475, 476, 477, 478, 479, 480, 481, 482, 483, 484, 485, 486, 487, 488, 489, 490, 491, 492, 493, 494, 495, 496, 497, 498, 499, 500, 501, 502, 503, 504, 505, 506, 507, 508, 509, 510, 511, 512, 513, 514, 515, 516, 517, 518, 519, 520, 521, 522, 523, 524, 525, 526, 527, 528, 529, 530, 531, 532, 533, 534, 535, 536, 537, 538, 539, 540, 541, 542, 543, 544, 545, 546, 547, 548, 549, 550, 551, 552, 553, 554, 555, 556, 557, 558, 559, 560, 561, 562, 563, 564, 565, 566, 567, 568, 569, 570, 571, 572, 573, 574, 575, 576, 577, 578, 579, 580, 581, 582, 583, 584, 585, 586, 587, 588, 589, 590, 591, 592, 593, 594, 595, 596, 597, 598, 599, 600, 601, 602, 603, 604, 605, 606, 607, 608, 609, 610, 611, 612, 613, 614, 615, 616, 617, 618, 619, 620, 621, 622, 623, 624, 625, 626, 627, 628, 629, 630, 631, 632, 633, 634, 635, 636, 637, 638, 639, 640, 641, 642, 643, 644, 645, 646, 647, 648, 649, 650, 651, 652, 653, 654, 655, 656, 657, 658, 659, 660, 661, 662, 663, 664, 665, 666, 667, 668, 669, 670, 671, 672, 673, 674, 675, 676, 677, 678, 679, 680, 681, 682, 683, 684, 685, 686, 687, 688, 689, 690, 691, 692, 693, 694, 695, 696, 697, 698, 699, 700, 701, 702, 703, 704, 705, 706, 707, 708, 709, 710, 711, 712, 713, 714, 715, 716, 717, 718, 719, 720, 721, 722, 723, 724, 725, 726, 727, 728, 729, 730, 731, 732, 733, 734, 735, 736, 737, 738, 739, 740, 741, 742, 743, 744, 745, 746, 747, 748, 749, 750, 751, 752, 753, 754, 755, 756, 757, 758, 759, 760, 761, 762, 763, 764, 765, 766, 767, 768, 769, 770, 771, 772, 773, 774, 775, 776, 777, 778, 779, 780, 781, 782, 783, 784, 785, 786, 787, 788, 789, 790, 791, 792, 793, 794, 795, 796, 797, 798, 799, 800, 801, 802, 803, 804, 805, 806, 807, 808, 809, 810, 811, 812, 813, 814, 815, 816, 817, 818, 819, 820, 821, 822, 823, 824, 825, 826, 827, 828, 829, 830, 831, 832, 833, 834, 835, 836, 837, 838, 839, 840, 841, 842, 843, 844, 845, 846, 847, 848, 849, 850, 851, 852, 853, 854, 855, 856, 857, 858, 859, 860, 861, 862, 863, 864, 865, 866, 867, 868, 869, 870, 871, 872, 873, 874, 875, 876, 877, 878, 879, 880, 881, 882, 883, 884, 885, 886, 887, 888, 889, 890, 891, 892, 893, 894, 895, 896, 897, 898, 899, 900, 901, 902, 903, 904, 905, 906, 907, 908, 909, 910, 911, 912, 913, 914, 915, 916, 917, 918, 919, 920, 921, 922, 923, 924, 925, 926, 927, 928, 929, 930, 931, 932, 933, 934, 935, 936, 937, 938, 939, 940, 941, 942, 943, 944, 945, 946, 947, 948, 949, 950, 951, 952, 953, 954, 955, 956, 957, 958, 959, 960, 961, 962, 963, 964, 965, 966, 967, 968, 969, 970, 971, 972, 973, 974, 975, 976, 977, 978, 979, 980, 981, 982, 983, 984, 985, 986, 987, 988, 989, 990, 991, 992, 993, 994, 995, 996, 997, 998, 999, 1000)

SECTION 2 - TO BE COMPLETED BY ALL ENTITIES

22. Name of Select Agent or Toxin: _____ 23. Description of Agent (e.g., strain, ATCC #): _____ 24. Quantity / Amount: _____

A: _____ B: _____ C: _____

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Transparency and Information Sharing

Non-disclosure of Information

Public Health Security & Bioterrorism Preparedness and Response Act of 2002, Title II: Subtitle A, Section 201

days.

“(h) DISCLOSURE OF INFORMATION.—

“(1) NONDISCLOSURE OF CERTAIN INFORMATION.—No Federal agency specified in paragraph (2) shall disclose under section 552 of title 5, United States Code, any of the following:

“(A) Any registration or transfer documentation submitted under subsections (b) and (c) for the possession, use, or transfer of a listed agent or toxin; or information derived therefrom to the extent that it identifies the listed agent or toxin possessed, used, or transferred by a specific registered person or discloses the identity or location of a specific registered person.

“(B) The national database developed pursuant to subsection (d), or any other compilation of the registration or transfer information submitted under subsections (b)

and (c) to the extent that such compilation discloses site-specific registration or transfer information.

“(C) Any portion of a record that discloses the site-specific or transfer-specific safeguard and security measures used by a registered person to prevent unauthorized access to listed agents and toxins.

“(D) Any notification of a release of a listed agent or toxin submitted under subsections (b) and (c), or any notification of theft or loss submitted under such subsections.

“(E) Any portion of an evaluation or report of an inspection of a specific registered person conducted under subsection (f) that identifies the listed agent or toxin possessed by a specific registered person or that discloses the identity or location of a specific registered person if the agency determines that public disclosure of the information would endanger public health or safety.

Background

- ❑ **For security reasons, FSAP generally has not released to the public certain information about registered entities, including:**
 - Site-specific information about their possession of select agents and toxins
 - The location where the select agents and toxins are registered for storage and use (i.e., laboratory)
 - The names of individuals working with select agents and toxins
 - Site-specific information submitted on an APHIS/CDC form, or
 - Site-specific information related to inspection reports
- ❑ **While transparency is important, we constantly need to balance the need for transparency and disclosure versus the potential security concerns that could arise from sharing entity-specific information**

Considerations

- ❑ Goal is to include as much information as possible without raising any potential security concerns
- ❑ By reporting data at an aggregate level, the intent is that it would not be possible to identify specific entities or link the data back to the work of any one particular entity

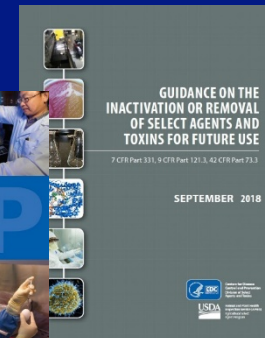
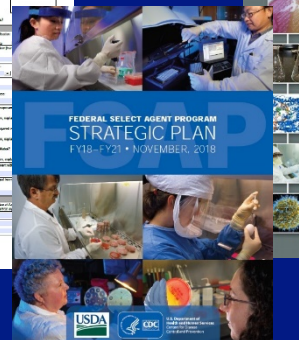
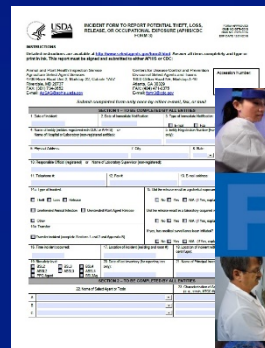
What We Do

- ❑ **For the public:**
 - FSAP website
 - Publication of aggregate annual program data, including:
 - *Annual Report of the Federal Select Agent Program*
 - *FSAP Inspection Report Processing Annual Summary*
 - Participation in major national and international meetings
- ❑ **For the regulated community:**
 - Webinars and trainings
 - Annual Responsible Official Workshop
 - Sponsorship of third-party forum via ABSA International
- ❑ **For state health officials:**
 - Information sharing

FSAP Website

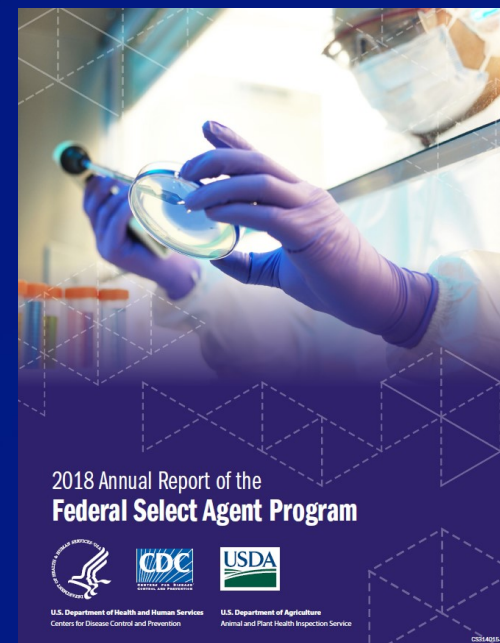
- Includes a variety of program information and resource, including:
 - Regulations
 - Frequently Asked Questions
 - Policies
 - Guidance documents
 - Forms
 - Publications
 - Reports

www.selectagents.gov



Annual Report of the Federal Select Agent Program

- ❑ Annual report of aggregate program data
- ❑ Provides a look at both the regulatory functions of the program, as well as compliance with the select agent regulations at laboratories across the nation
- ❑ Initiated with analysis of 2015 data
- ❑ Most recent analysis published in January 2020
- ❑ Reflects FSAP's ongoing commitment to increasing transparency
- ❑ Available at <https://www.selectagents.gov/annualreport2018.html>



FEDERAL SELECT AGENT PROGRAM 2018 ANNUAL REPORT | KEY STATISTICS

The *2018 Annual Report of the Federal Select Agent Program* continues to provide insight into the regulatory activities of the Federal Select Agent Program (FSAP). The report includes a look at both the regulatory functions of the program, as well as compliance with the select agent regulations at laboratories across the nation. This annual report is FSAP's fourth report of aggregate program data, and reflects the program's ongoing commitment to transparency and increasing understanding of the program.

- FSAP is managed jointly by the Centers for Disease Control and Prevention's Division of Select Agents and Toxins and the Animal and Plant Health Inspection Service's Agriculture Select Agent Services
- FSAP regulates the possession, use, and transfer of biological select agents and toxins (BSAT) so that important work with potentially dangerous and deadly pathogens is conducted as safely and securely as possible
- BSAT are materials that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products

253
ENTITIES WERE REGISTERED WITH FSAP

- 33% ACADEMIC
- 17% COMMERCIAL
- 15% FEDERAL GOVERNMENT
- 29% NON-FEDERAL GOVERNMENT
- 6% PRIVATE

51% of entities were registered for Tier 1* BSAT

LAB BIOSAFETY LEVELS (BSL)

ENTITIES MAY HAVE MULTIPLE TYPES

- 30% had BSL-2 and/or ABSL-2 labs
- 79% had BSL-3 and/or ABSL-3 labs
- 3% had BSL-4 and/or ABSL-4 labs

TOP REGISTERED AGENTS BY AGENCY

CDC's Division of Select Agents and Toxins

- Brucella melitensis*
- Brucella suis*
- Brucella abortus*
- Bacillus anthracis* (Pasteur strain)
- Francisella tularensis**

APHIS's Agriculture Select Agent Services

- Newcastle disease virus
- Avian influenza virus
- Ralstonia solanacearum*
- Xanthomonas oryzae*
- Brucella abortus*

COMPLIANCE & ENFORCEMENT

- 3** total entities participated in a corrective action plan (including **1** entity that newly agreed to participate in 2018)
- 0** total entities had fully suspended registrations (with **5** entities newly put under partial suspension in 2018)
- 9** matters were shared with the Federal Bureau of Investigation for potential investigation (FBI determined no action was needed in any of those cases)
- 4** entities were referred to the HHS Office of Inspector General or APHIS Investigative and Enforcement Services

THEFT, LOSS, OR RELEASE

- 0** thefts reported
- 8** reports of losses determined to be inventory accounting errors or inadvertent destruction of BSAT
- 0** occupational exposures resulting in illness, death, or transmission, out of the **185** incidents reported involving occupational exposures

TRANSFER APPROVALS: 192 DSAT | 61 AgSAS

- 26%** of the transfers were from unregistered entities to registered entities, and occurred after the identification of BSAT in a diagnostic specimen or represented imports from outside the U.S.

206

TOTAL INSPECTIONS CONDUCTED BY FSAP

- 149** by DSAT
- 18** by AgSAS
- 39** joint DSAT & AgSAS

2.5

AVERAGE DURATION (IN DAYS) FOR INSPECTION

Range of **1 to 10** days

8,434

ACTIVE INDIVIDUAL SECURITY RISK ASSESSMENTS

Denied access for **24** individuals

KEY ABBREVIATIONS:

FSAP: Federal Select Agent Program DSAT: Division of Select Agents and Toxins BSAT: Biological select agents and toxins ABSL: Animal biosafety level
CDC: Centers for Disease Control and Prevention APHIS: Animal and Plant Health Inspection Service AgSAS: Agriculture Select Agent Services

*Tier 1 agent, those that pose the greatest risk through misuse

FSAP 2018: Key Facts

- ❑ **253 registered entities**
- ❑ **206 inspections conducted**
- ❑ **8,434 active individual security risk assessments**
 - Denied access for 24 individuals
- ❑ **No potential exposures resulted in illness, death, or transmission in laboratories or the community**

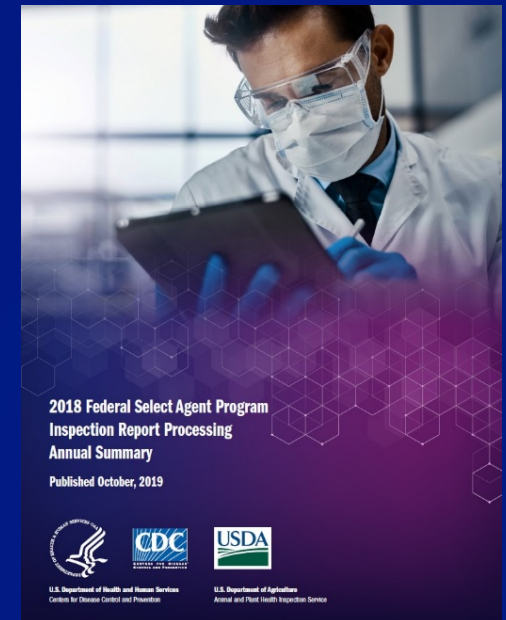
Enforcement Actions, 2018

- ❑ 3 total entities participated in a Corrective Action Plan**
 - Including 1 entity that newly agreed to participate**
- ❑ 0 entities had fully suspended registrations**
 - With 5 entities newly put under partial suspension**
- ❑ 9 matters were shared with the FBI for potential investigation**
 - FBI determined no action was needed in any of those cases**
- ❑ 4 entities were referred to the HHS Office of Inspector General or APHIS Investigative and Enforcement Services**

FSAP Inspection Report Processing Annual Summaries

- ❑ Annual report initiated with program analysis of 2015 DSAT data; now includes AgSAS data as well
- ❑ FSAP goal is to send all inspection reports to entities within 30 business days – analysis looks at how well the program is meeting this goal
 - Does not include entity-specific information
- ❑ Most recent analysis released in October 2019; found that in 2018, nearly all inspection reports (93%) were sent to entities within FSAP’s goal of 30 business days
 - Results underscore the program’s continued commitment to provide timely feedback

Reports are available at
<https://www.selectagents.gov/publications.html>



Outreach

- ❑ **FSAP leadership routinely speaks at major national and international meetings, such as:**
 - ABSA
 - ASM Biothreats
 - NIH Regional/National Biocontainment Lab Annual Meeting
 - Arizona Biosecurity Workshop
 - International Group of Experts on Biosafety and Biosecurity Regulation (IGEBBR)

- ❑ **FSAP information booth regularly exhibits at major meetings, such as:**
 - ABSA
 - ASM Microbe
 - ASM Biothreats

- ❑ **Routinely hold webinars to provide information and/or trainings on key topics (e.g., policy changes, updates to the program's information technology system)**



Responsible Official (RO) Workshop

- ❑ Multi-day event brings FSAP staff and the regulated community together – 130 attendees in 2019
- ❑ Agenda topics generally include discussions related to compliance with the select agent regulations
- ❑ Format includes presentations and small group discussion session
- ❑ Provides an opportunity for ROs to network with colleagues



ABSA Independent Forum

- ❑ FSAP provides continued support of an independent forum via ABSA International to encourage routine peer-to-peer sharing of information and best practices**
- ❑ Through this mechanism, ABSA provides an online discussion forum, annual in-person workshop, and webinars for the regulated community**
- ❑ Effort established in 2017 as a part of FSAP efforts to improve its service to the regulated community and address program recommendations**

Information Sharing with State Health Officials

- ❑ **FSAP has established a process to provide state health officials with the current list of entities within their state to promote state public health preparedness and provide awareness of entities in their state**

Discussion

www.selectagents.gov

CDC: Irsat@cdc.gov or 404-718-2000

APHIS: AgSAS@usda.gov or
301-851-3300 option 3 (voice only)

