



# Select Agent Program Overview

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**Director**

Division of Select Agents & Toxins  
Coordinating Office for Terrorism Preparedness  
and Emergency Response

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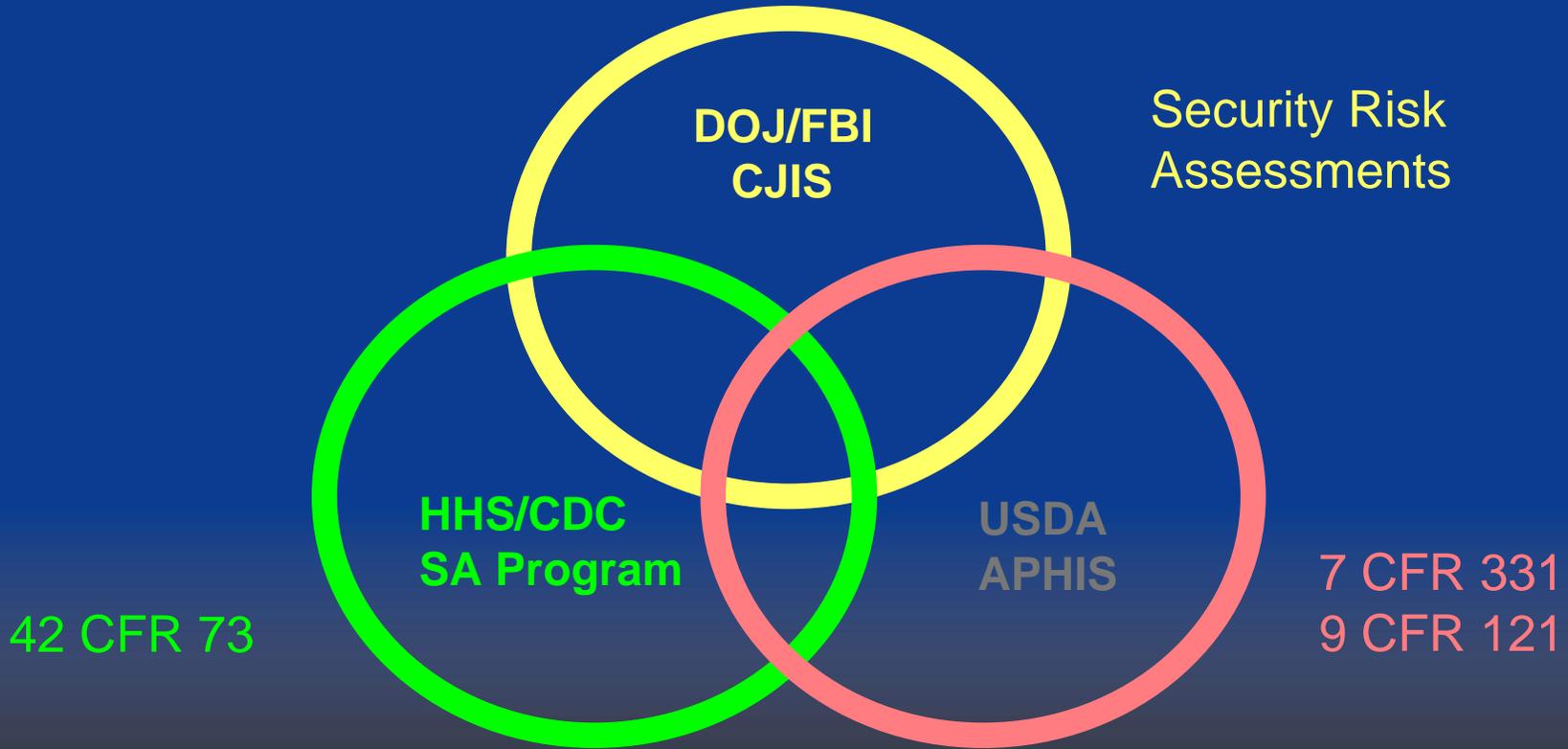
# Select Agent Program Regulatory Mandates



- **Antiterrorism and Effective Death Penalty Act of 1996  
(Signed April 24, 1996)**
  - ◆ 42 C.F.R. 72.6 – Additional Requirements for facilities transferring and receiving Select Agents (Effective April 15, 1997)
  
- **Public Health Security and Bioterrorism Preparedness and Response Act 2002, Title II (Signed June 12, 2002)**
  - ◆ 42 C.F.R. Part 73 – Possession Use, and Transfer of Select Agents and Toxins (IFR Effective February 7, 2003)
  - ◆ 42 C.F.R. Part 73 – Possession Use, and Transfer of Select Agents and Toxins (FR Effective April 18, 2005)



# Federal Partners



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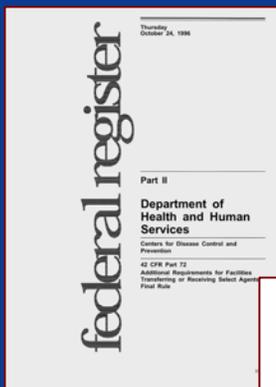
# Coordination of CDC & APHIS Activities



- Lead Agency-single point of contact
  - ◆ Overlap + HHS-only and/or USDA-only
  - ◆ Send all registration forms to either CDC or APHIS
- Responsible for coordinating all activities and communications with respect to the entity's registration
  - ◆ Coordination of inspections
- Responsible for providing harmonized guidance to regulated entities



# What are the Select Agent regulations?



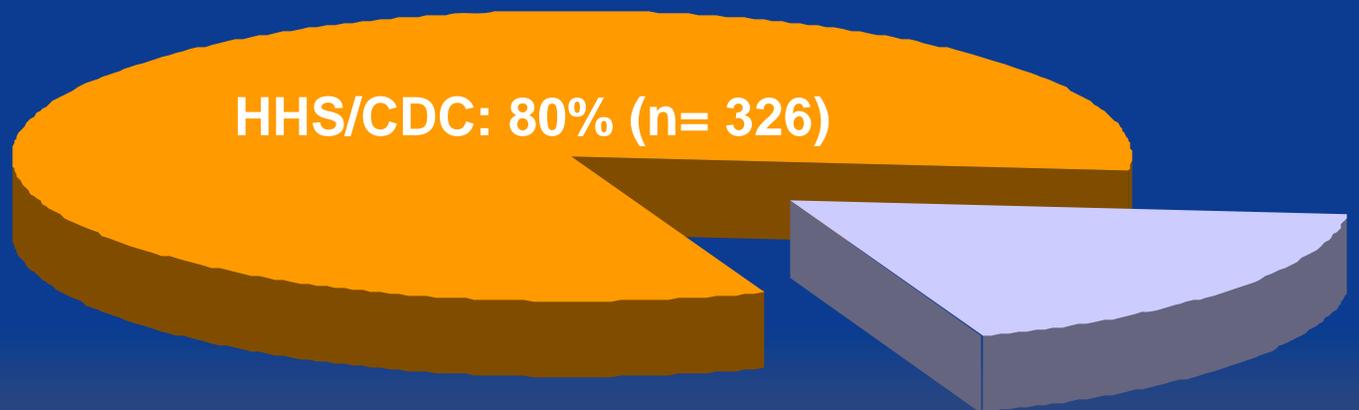
- Interim Final Rule: “Possession Use, and Transfer of Select Agents and Toxins” (42 CFR 73, 9 CFR 121, and 7 CFR 331)
  - ◆ Effective February 7, 2003
- Final Rule: “Possession, Use, and Transfer of Select Agents and Toxins” (42 CFR 73, 9 CFR 121, and 7 CFR 331)
  - ◆ Effective April 18, 2005
- Interim Final Rule: “Reconstructed Replication Competent Forms of the 1918 Pandemic Influenza Virus Containing Any Portion of the Coding Regions of All Eight Gene Segments” (42 CFR 73)
  - ◆ Effective October 20, 2005



# Laboratories Registering a Select Agent with HHS/CDC or USDA/APHIS



(Total = 409 as of 9/26/2007 )

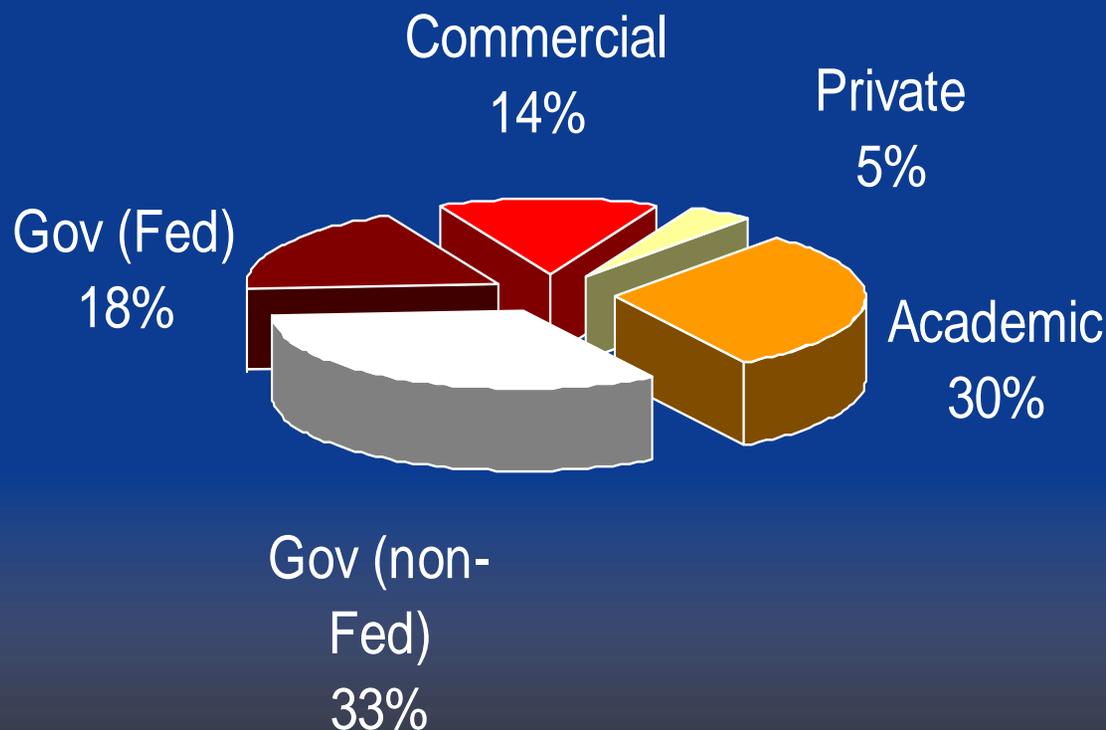


USDA/APHIS: 20% (n=83)



# Types of Laboratories Registered

(Total = 409 as of 9/26/2007)

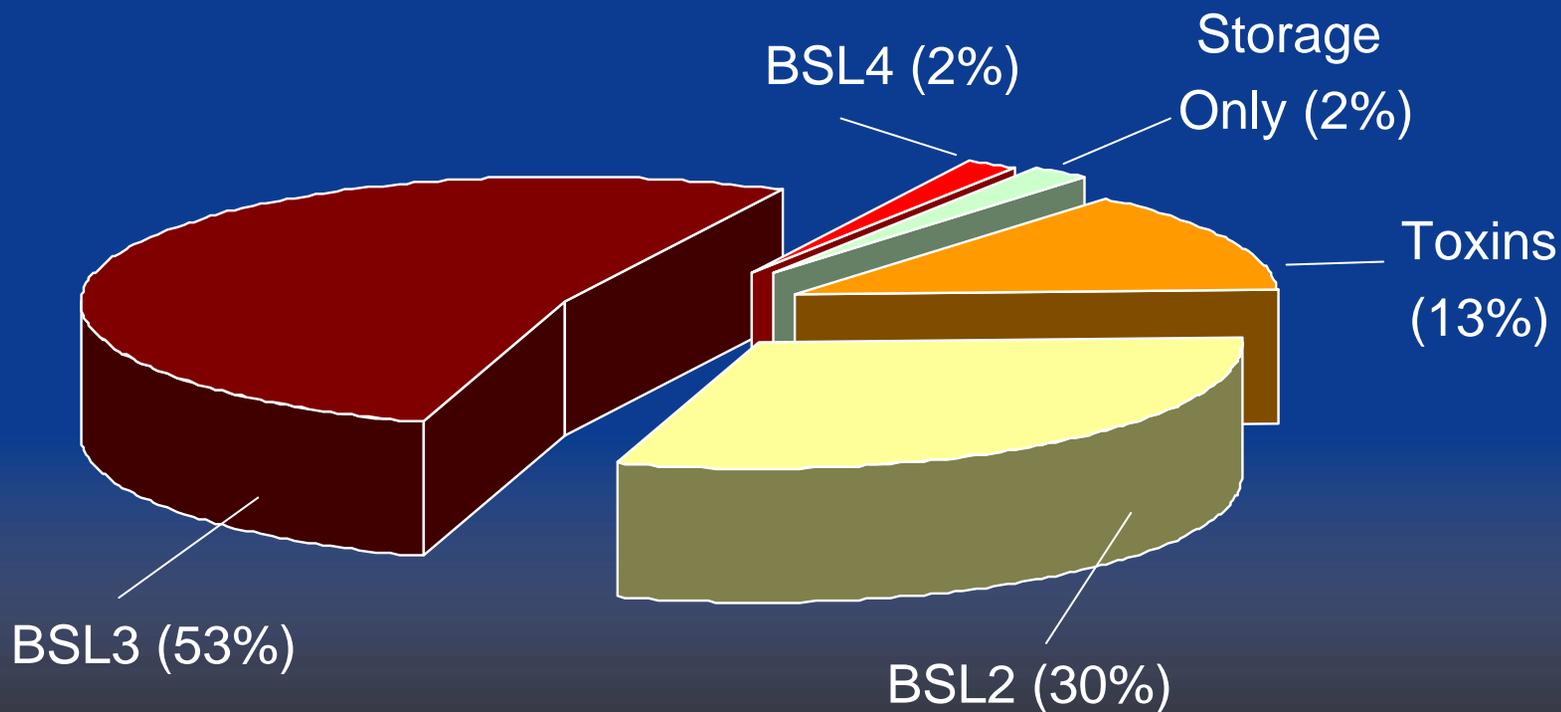




# Types of Laboratories Registered with APHIS & CDC



(Total = 1,850 as of 9/26/2007)

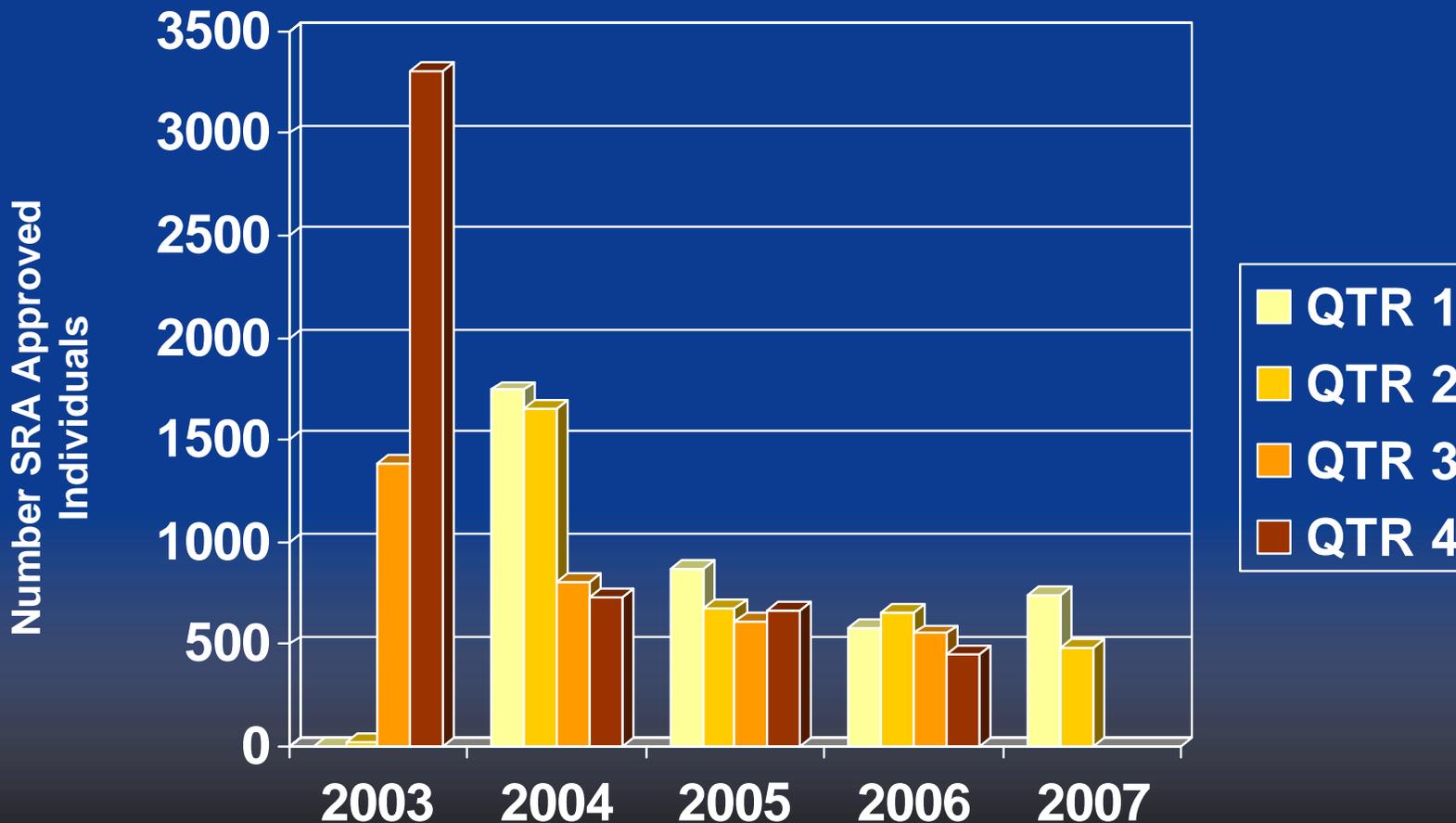




# SRA- Approved Individuals at All Entities by Quarter



(Total = 16,493 as of 09/26/07)

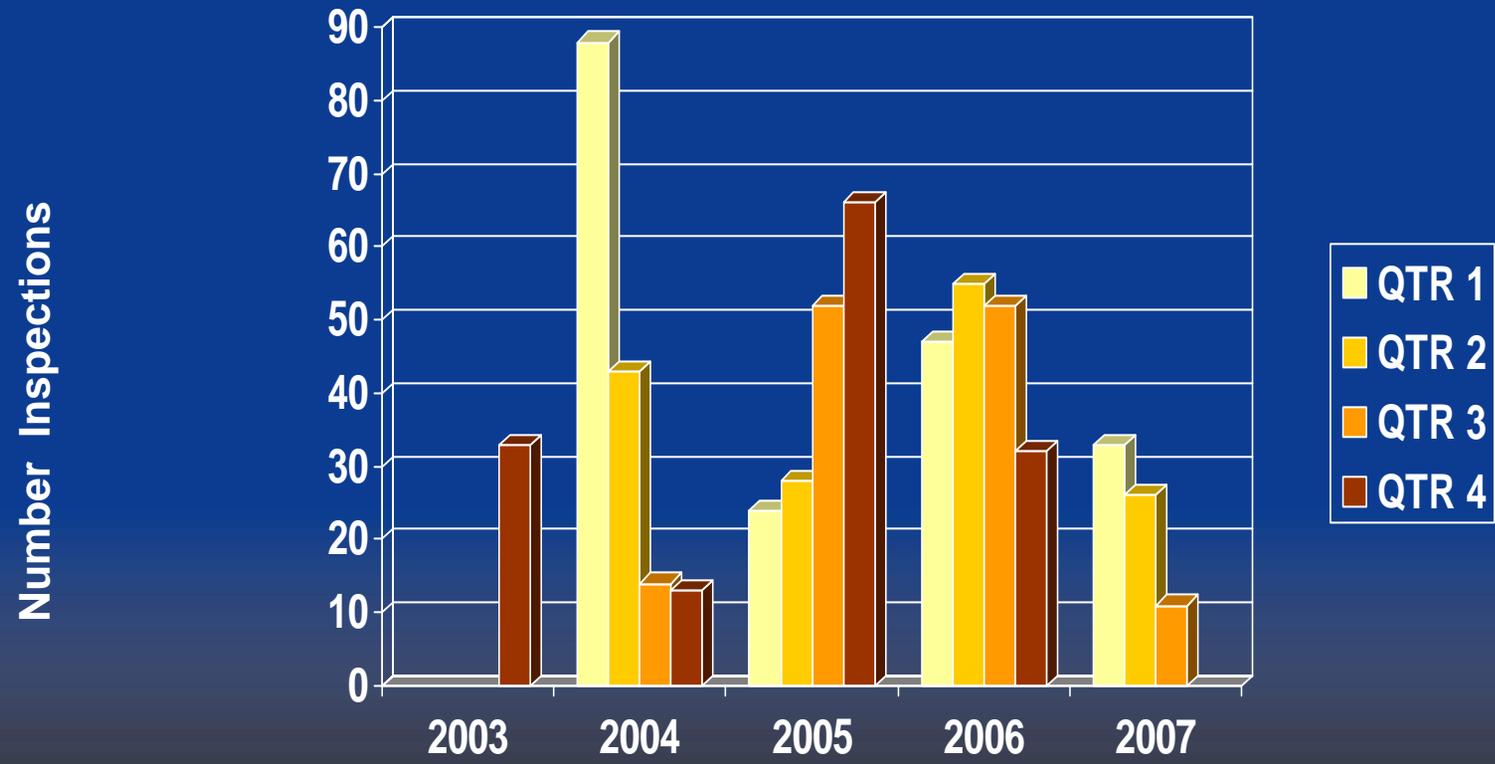




# Inspections Conducted at All Registered Entities by Year



(Total = 615 as of 09/26/2007)

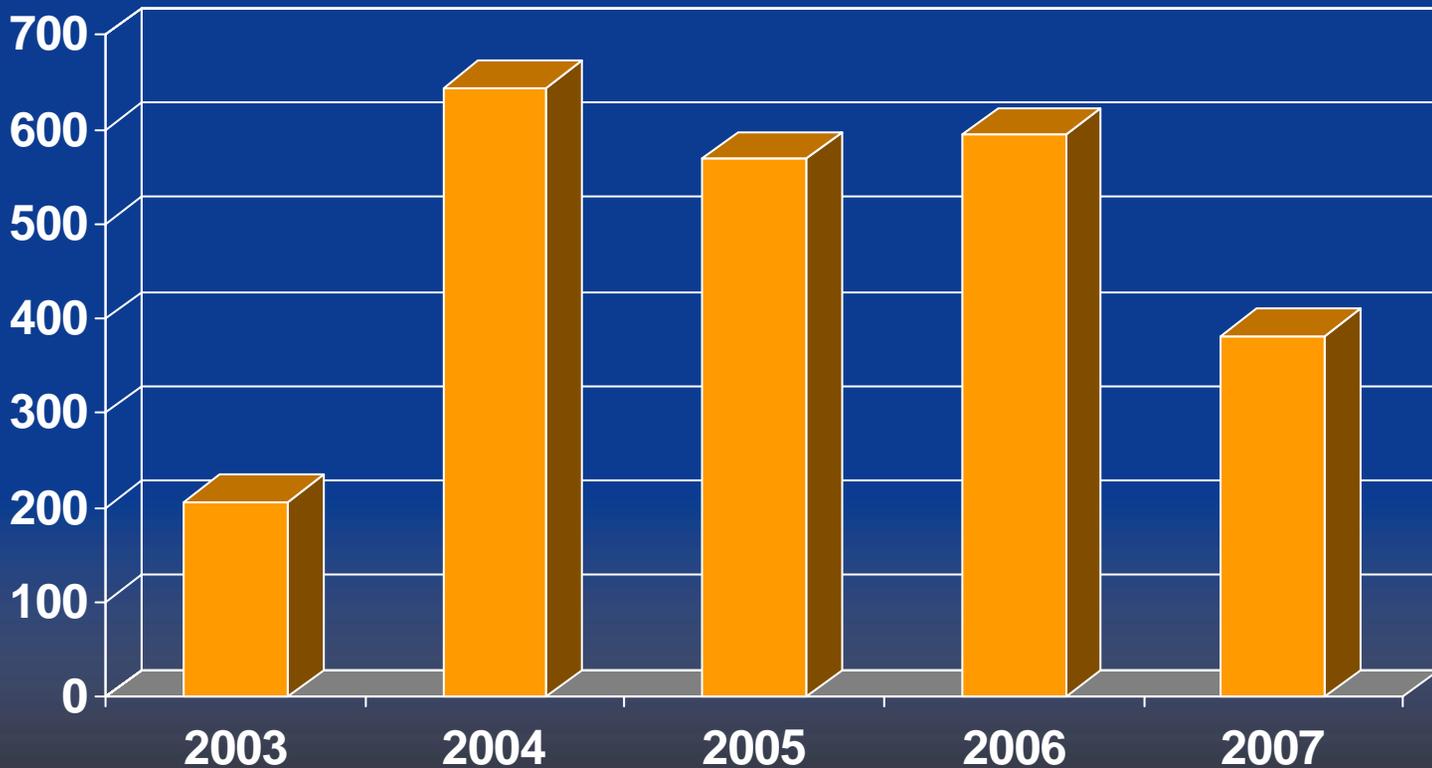




# Transfer Approvals of Select Agents by Year



(Total = 2,395 as of 09/26/07)





# Select Agent Enforcement

- HHS - Office of Inspector General
- USDA - Investigative and Enforcement Services
- DOJ - FBI



# Select Agent Enforcement

- Administrative Actions
  - ◆ Denial of application
  - ◆ Revocation or suspension of registration
- Civil Monetary 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



# HHS Non-Compliance Statistics



- 5 cases of administrative actions
  - ◆ 4 denials
  - ◆ 1 suspension
  
- 8 cases referred to FBI for possible criminal actions
  
- 37 cases referred to HHS-OIG
  - ◆ 10 cases resulted in Civil Monetary Penalties
    - ❖ \$799,000
    - ❖ Unauthorized transfers,
    - ❖ Possession without registration,
    - ❖ Biosafety and security concerns



# Positive Aspects of Implementation of the Select Agent Regulations



- Identification of entities possessing these agents.
- Strengthened safety and security requirements for all entities working with these agents.
- Required national reporting of theft, loss, or release of these agents.
- Enhanced the nation's ability to prevent domestic and international terrorism while fostering legitimate research.



# Additional Resources



## ■ CDC Select Agent Program

- ◆ Phone 404-718-2000
- ◆ Fax 404-718-2096
- ◆ E-mail [lrsat@cdc.gov](mailto:lrsat@cdc.gov)

◆ Web site <http://www.cdc.gov/od/sap>

## ■ USDA/APHIS

- ◆ Phone 301-734-3277
- ◆ Fax 301-734-3652
- ◆ Web site

<http://www.aphis.usda.gov/programs/ag-selectagent/index.html>

## ■ FBI

- ◆ Phone 304-625-4900
- ◆ Fax 304-625-5393

◆ Web site <http://www.fbigov/hq/cjisd/cjis.htm>



# National Select Agent Registry:

[www.selectagents.gov](http://www.selectagents.gov)

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