

# Preparing for Inspections



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APHIS/CDC Select Agent Workshop

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



# Authority to Inspect (42 CFR §73.18)

- ❑ “Without prior notification, the HHS Secretary, shall be allowed to inspect any site at which activities regulated by this part are conducted and shall be allowed to inspect and copy any records relating to the activities covered by this part.”
- ❑ Inspections may be announced or unannounced

# Types of Inspections

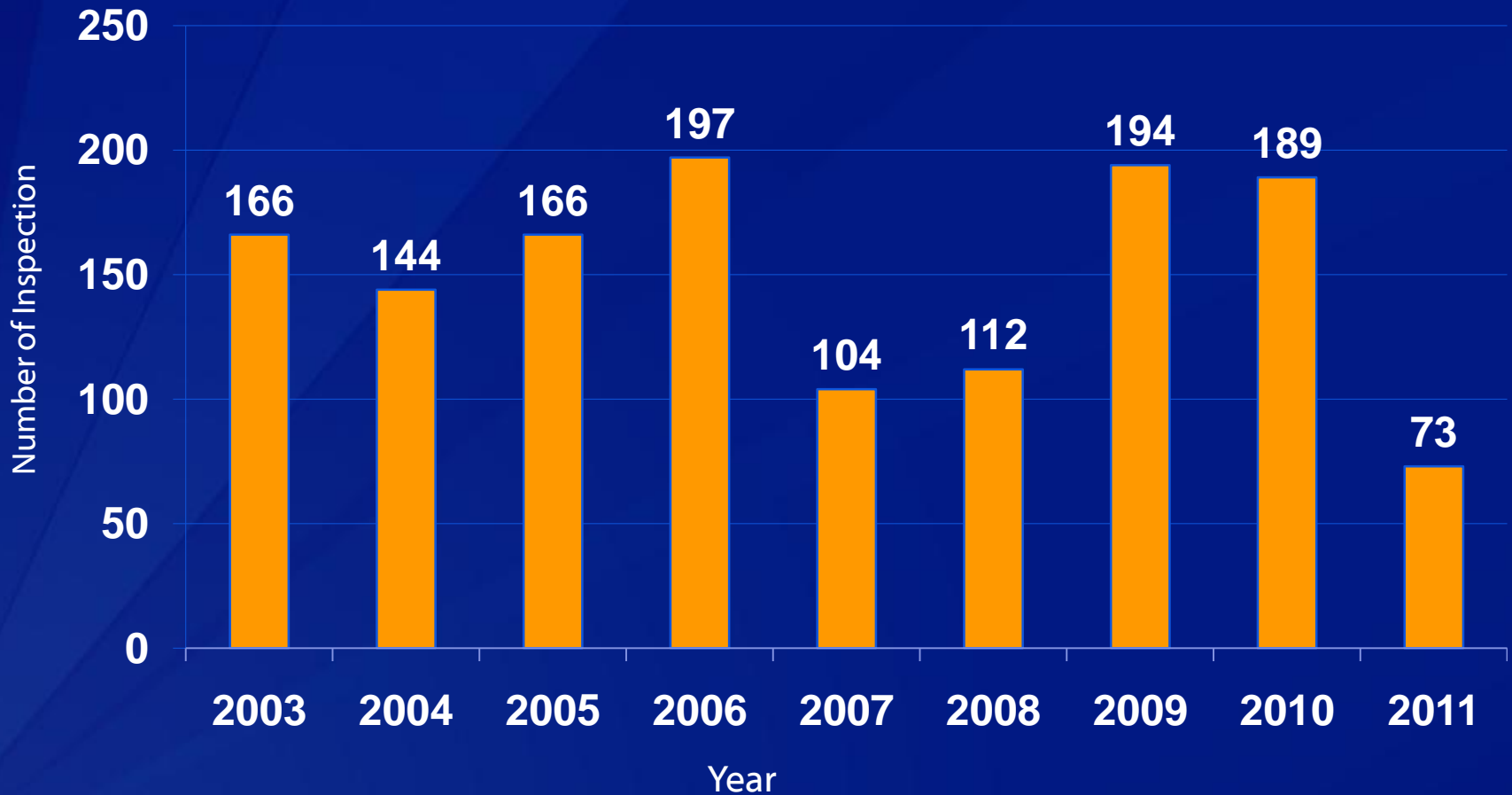
- ❑ Routine Inspections
  - New application;
  - Renewal of certificate of registration;
  - Evaluation of new space (commissioning) ;
- ❑ Verification Inspections
- ❑ Non-routine Inspections
  - Compliance issue;
  - Response to concern or complaint;
  - Theft, loss, or release;

# Verification Inspections

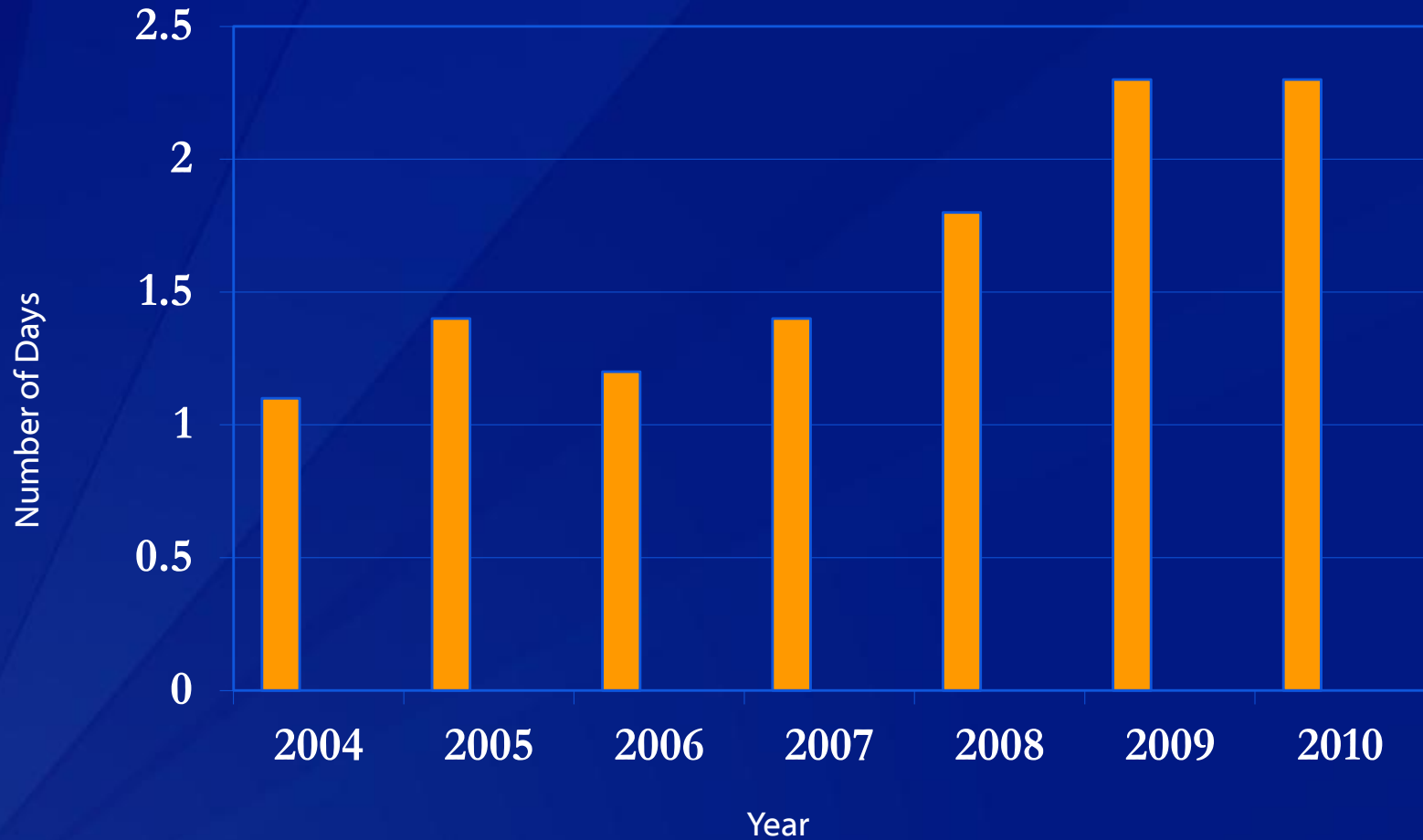
- ❑ In 2011, the Centers for Disease Control and Prevention (CDC) Select Agent Program implemented a pilot study of unannounced inspections to assess compliance with 42 CFR Part 73.
  - Resolution of past inspection deficiencies
  - Review of selected inspection documents
  - Tour of facility
  - Short in-briefing and out-briefings conducted
  - Tend to be shorter in duration
  - Inspection reports issues
- ❑ May be announced or unannounced

# Select Agent Inspections Conducted by Calendar Year

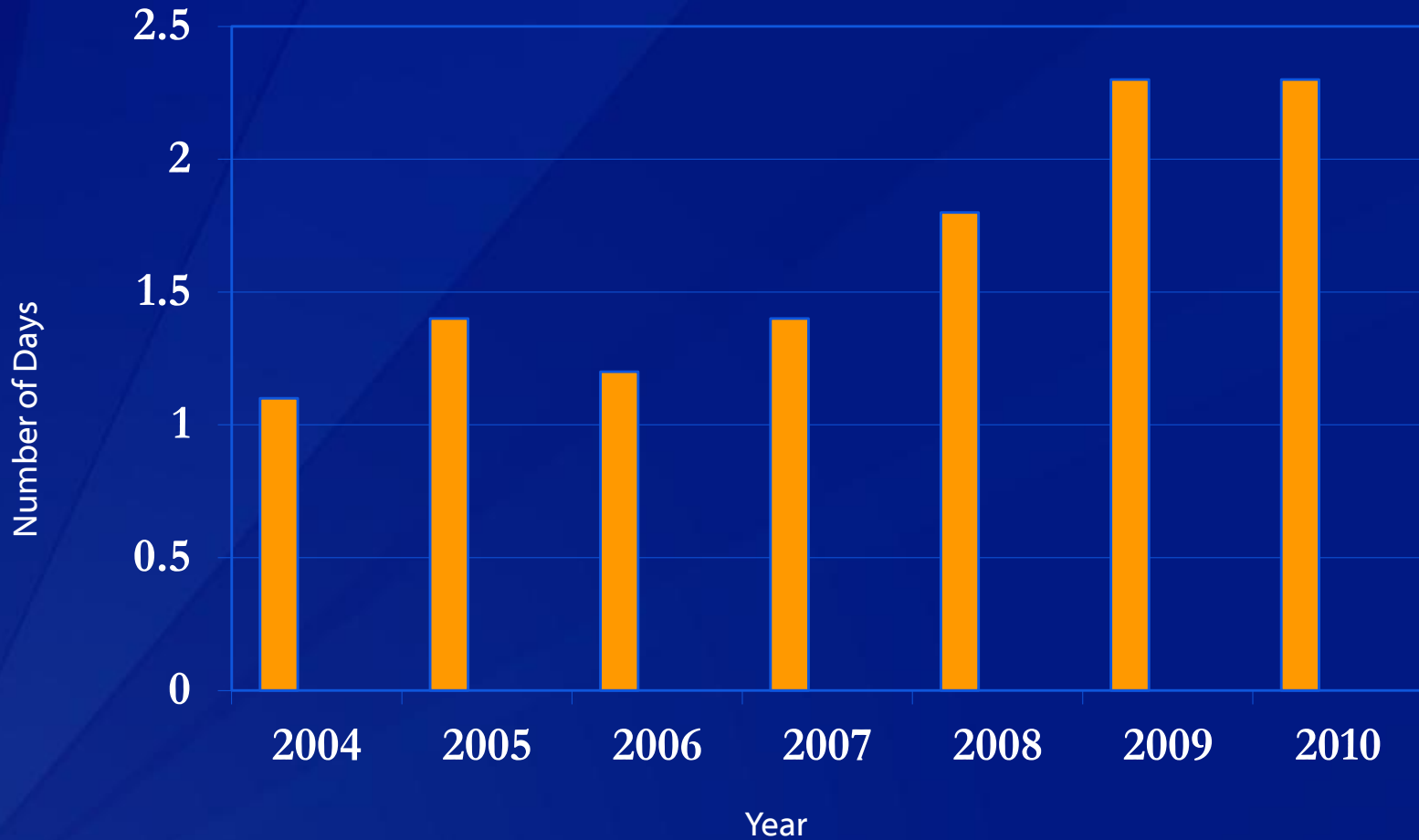
(Total=1345; As of March 31, 2011)



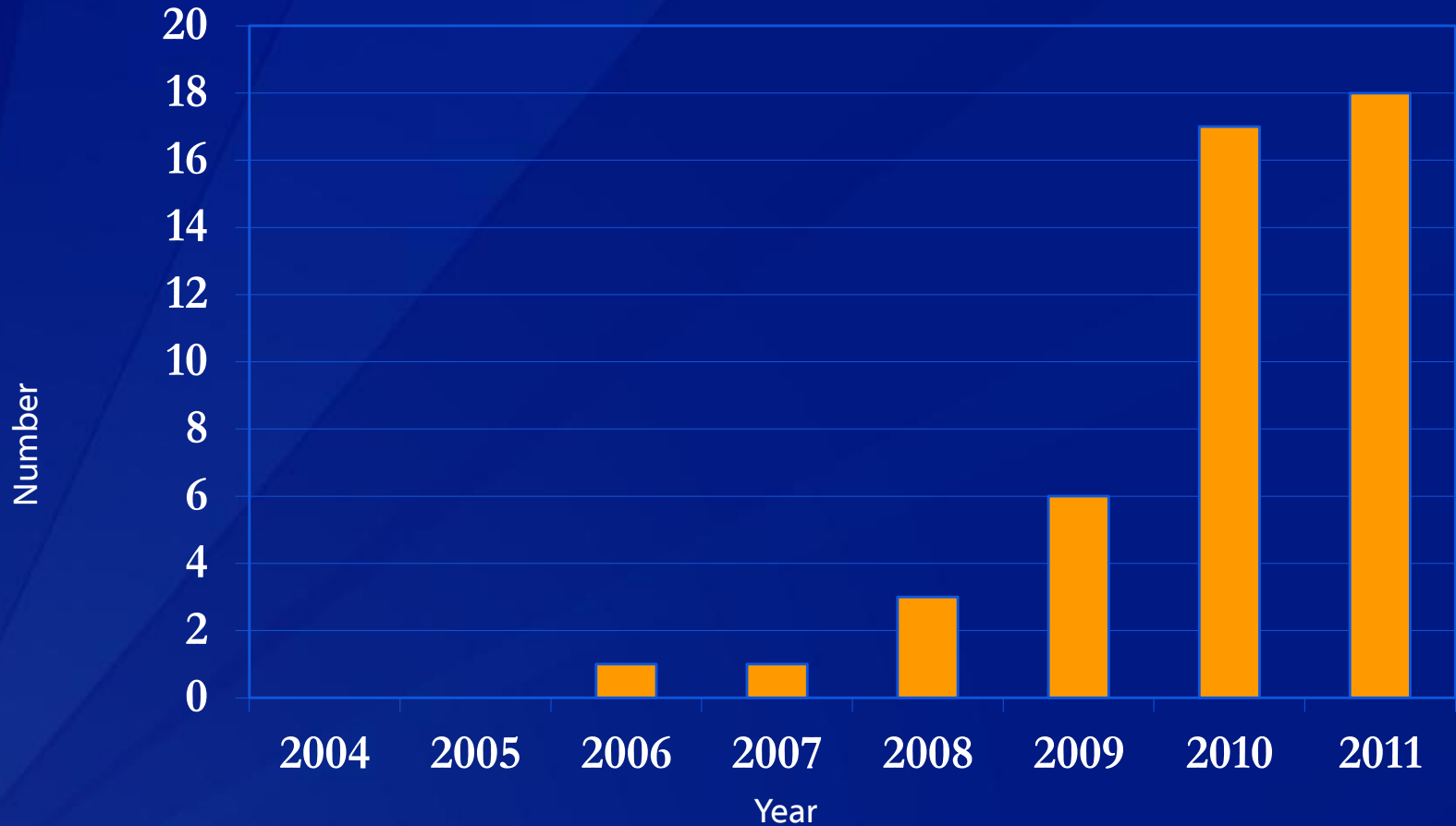
# Average Days per Inspection (2004-2010)



# Average Inspectors per Inspection (2004-2010)



# Number of Unannounced Inspections (As of March 31, 2011)





# **INSPECTION PROCESS**

# CDC Inspection Process - Routine Inspections

- ❑ Opening Introduction
- ❑ Tour facility
  - Registered laboratories and storage rooms
  - Inventory audit
  - HVAC
  - Overall physical security
  - Security facilities
  - Shipping and receiving
- ❑ Review all documents related to Select Agents and Toxins Regulations
- ❑ Employee and Responsible Official Interviews
- ❑ Outbriefing

# **EVOLUTION**

# Evolution of CDC Select Agent Program

## □ Anonymous Reporting

- HHS, Office of Inspector General (OIG) hotline
- Mechanism to report safety, security, or other concerns associated with select agents and toxins confidentially
- Phone: 1-800-447-8477; Fax: 1-800-223-8164
- E-mail: [HHSTIPS@oig.hhs.gov](mailto:HHSTIPS@oig.hhs.gov)
- Web: <http://oig.hhs.gov/fraud/hotline>
- Mail: Office of Inspector General

Department of Health & Human Services

Attn: Hotline

P.O. Box 23489

Washington, DC 20026

# Evolution of CDC Select Agent Program

- ❑ More rigorous oversight
  - Enhanced inspections
    - Pre-visit document review
    - Employee interviews
    - From “Trust” to “Trust, but Verify”
  - Increase in number of inspections (routine and non-routine)
  - Entity Performance Improvement Plan
  - Internal entity risk assessment
    - Identifies entities for more extensive oversight
- ❑ Increased effort to coordinate inspections with other federal agencies

# Coordination with Partners

- ❑ CDC-led entities with USDA-only agents: Animal and Plant Health Inspection Service (APHIS) inspector to join CDC team
- ❑ APHIS-led entities with HHS-only agents: CDC inspector to join APHIS team
- ❑ Department of Homeland Security
- ❑ Department of Defense:
  - Army Inspector General
  - Navy
  - Air Force

# **PREPARING FOR INSPECTIONS**

# Preparing for Inspections

- ❑ Visit National Select Agent Website:  
[www.selectagents.gov/Resources](http://www.selectagents.gov/Resources)
  - Facility Inspection Video
  - Checklists
  - Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5<sup>th</sup> edition
  - Long Term Storage
  - Security Related Information



# Preparing for Inspections (continued)

- ❑ Responsible Official (42 CFR § 73.9)
  - Be familiar with requirements
  - Have the authority and responsibility to act on behalf of the entity
  - Ensure compliance with the requirements of 42 CFR 73
- ❑ Develop an ongoing process
- ❑ Ensure accuracy of statements in responses to prior inspection deficiencies

# Preparing for Inspections (continued)

- ❑ Complete annual requirements each year
  - Inspections
  - Review of plans (biosafety, incident response, security, chemical hygiene for toxins)
  - Drills and exercises
  - Training
  - Facility requirements
- ❑ Make plans specific to your entity

# Preparing for Inspections (continued)

- ❑ Conduct drills that test the plans; revise and review plan after the drill, if needed
- ❑ Ensure that inspections cover “all parts”
  - Implement and document corrective actions from annual inspections, if needed
- ❑ Devise systems to ensure accuracy of records (e.g., review of access records)
- ❑ Devise systems to ensure accuracy of inventory (e.g., inventory audits)

# Preparing for Inspections

## (continued)

- ❑ Ensure that training has been effective and well documented
  - Curriculum described
  - Means used to verify understanding of training
  - Records maintained
- ❑ Visitor training in place
- ❑ Training addresses the needs of the individual, the work they will do, and the risks

# Preparing for Inspections (continued)

- ❑ Ensure there is a plan for facility issues
  - Annual verification of facility design and operational parameters, including failure mode testing
  - Annual HEPA filter leak testing
  - Annual biosafety cabinet certifications
  - Other facility issues

# Discussion



## For more information, please contact Select Agent Program

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