AGRICULTURAL BIOTERRORISM PROTECTION

ACT OF 2002: IMPLEMENTATION OF

AGRICULTURAL SELECT AGENTS

Shannon Reid Hamm
Assistant Deputy Administrator
Policy and Program Development
Agricultural Bioterrorism Protection Act of 2002: Implementation of Agricultural Select Agents

Shannon Reid Hamm
Assistant Deputy Administrator
Policy and Program Development
Public Health Security & Bioterrorism
Preparedness and Response Act, 2002

Senator Daschle Received Anthrax Tainted Letter on October 9, 2001

Announced June 6, 2002 by President Bush

P.L. 107-188 Signed by President Bush, June 12, 2002
Public Health Security and Bioterrorism
Preparedness Response Act of 2002

❖ Purpose: To improve the ability of the US to prevent, prepare for, and respond to bioterrorism and other public health emergencies

❖ Subtitle B cited as the “Agricultural Bioterrorism Protection Act of 2002” expanded USDA authority

❖ Requirements
❖ List of biological agents and toxins
❖ Notification of Possession
❖ Registration for Possession, Use, and Transfer
❖ Exemptions
Promulgated Regulations: Mandated Partnerships...

- APHIS promulgated new regulations - expanded authority for intrastate movement (9 CFR Part 121 & 7 CFR Part 331)

- CDC promulgated new regulations (42 CFR Part 73)

- Department of Justice/Federal Bureau of Investigations (DOJ/FBI) implemented security risk assessments (SRA) on all entities and individuals
### ...and Timeline for Implementing Agricultural Select Agent Rule

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
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<tbody>
<tr>
<td>June 12, 2002</td>
<td>Review Statutory requirements</td>
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<tr>
<td>August 11, 2002</td>
<td>Promulgate Ag. Select Agent list &amp; notification requirements</td>
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<tr>
<td>October 10, 2002</td>
<td>Receive notification of Possession</td>
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<tr>
<td>December 9, 2002</td>
<td>Final interim rules</td>
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<td>MOU signed by USDA &amp; HHS Secretaries</td>
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<tr>
<td>February 14, 2002</td>
<td>Final interim rule effective</td>
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<tr>
<td>November 12, 2003</td>
<td>Full compliance by current possessors</td>
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<tr>
<td>Fall, 2004</td>
<td>Single Registration Program promulgated by USDA &amp; HHS</td>
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Phase In for Current Possessors of Select Agents

- February 11, 2003 effective date for regulations
- March 12, 2003 Registration applications submitted. Responsible Officials (RO) submit background materials to the DOJ/FBI
- June 12, 2003 security plans submitted
- September 12, 2003 security plans implemented
- November 12, 2003 full compliance upon application
Select Agent Program:
Meeting Deadlines

- Promulgated Interim Final Rules on November 3, 2003 – ensure all entities currently possessing and conducting research would not be disrupted on November 12, 2003

- By November 12, 2003 APHIS Issued Provisional Certificates of Registration for 75 entities

- Issued Denial letters for two entities due to safety concerns

- APHIS determined 17 entities were exempt from the regulations and another 17 entities withdrew their applications.
Entity Registration Depends on Designating Responsible Official

- Entity must designate a Responsible official (RO)
  - Must have the authority and control to ensure compliance with the regulations
- An alternate RO may also be designated
- RO submits personal information to APHIS
Responsible Official Role Extensive and Legally Binding

- RO submits required information to the DOJ/FBI for the security risk assessment (SRA)
  - RO security risk assessment tied to the entity
  - Individual SRA contingent on legitimate need for access & training

- RO submits entity and select agent information to APHIS (fondly known as the 4B)

- RO in charge of submitting the safety and security plans

- Civil penalty up to $250,000 for an individual and up to $500,000 for an entity

- Transfer of a select agent to an unregistered entity or person possible civil penalty (above) and/or imprisonment for up to 5 years
Next Steps for Select Agent Program

✓ APHIS/CDC set up working group to address all aspects of coordinating the select agent program.
  • Concurrence on overlap registration
  • Streamline registration process through defining “Lead Agency”
  • Outreach to regulated entities

✓ APHIS/CDC and the DOJ/FBI will ensure the SRA process is seamless.

✓ Review and republish lists of select agents toxins biennially or more often as needed.
How To Contact the Agencies Responsible for the Select Agent Program

- **USDA/APHIS**

- **HHS/CDC**
  - [www.cdc.gov](http://www.cdc.gov)

- **DOJ/FBI**
  - [www.fbi.gov/terrorinfo/bioterrorfd961.htm](http://www.fbi.gov/terrorinfo/bioterrorfd961.htm)