



United States Department of Agriculture
Animal and Plant Health Inspection Service
Plant Protection and Quarantine



APHIS' Select Agent List Process

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*Disclaimer: This is not a
presentation of the new Select
Agent List*



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USDA **APHIS**

Agricultural Bioterrorism Protection Act of 2002

- Established the Select Agent List
- Biennial Review of the List
- Statutory Criteria
 - The **effect of exposure** to the agent or toxin on animal or plant health, and on the **production and marketability** of animal or plant products;
 - The **pathogenicity** of the agent or the toxin and the methods by which the agent or toxin is **transferred** to animals or plants;
 - The availability and effectiveness of pharmacotherapies and prophylaxis to **treat and prevent** any illness caused by the agent or toxin; and
 - Any other elements that the Secretary considers appropriate to protect animal or plant health, or animal or plant products.



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USDA **APHIS**

History of the List

- Established in October 2002
- Republished March 2005
 - Removal of Soybean Rust and Plum Pox



Select Agent and Toxin Listing Group (SAL)


- Convened in April of 2006
- Consisted of members from various groups within USDA
 - APHIS
 - ARS
 - CSREES
 - FS
 - ERS
- What organisms?
- What criteria should be used?




List of Initial Organisms for Consideration

- Current Select Agents
- APS Emerging Pathogens List
- CAPS List
- Department of Commerce Export Control List
- Australia Group

Consolidated list had almost 70 pathogens as
potential Select Agents




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Rating Criteria Considerations

- Statutory Criteria
- APHIS Regulatory Criteria
- Economic Criteria
- CAPS Criteria
- APS Quantitative Ranking Criteria



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Rating Criteria

- **Host Value:** The economic value of major host(s) in US production and trade.
- **Pathogenicity/Biology:** The potential effect of the pathogen on US Agriculture with no control or mitigation measures.
- **Management:** The ability to respond and recover to the presence of the pathogen.
- **Regulatory Criteria:** The regulatory status of the pathogen.



Economic Analysis

- Determined the commodity host values for all pathogens on the list
- Determined the US export host values for all pathogens on the list
- Removed all pathogens with a total commodity/export host value less than \$400 million (Office of Management and Budget economically significant value)
 - For example, all coffee pathogens were removed



Ratings

- Distributed the shortened list of pathogens and the ranking criteria to Subject Matter Experts including, APS Emerging Pathogens Committee, CPHST, and ARS



Analysis and Discussion

- Rankings was compiled and analyzed.
- Top 30 organisms were discussed in greater depth.



Regulatory Process

- Proposed Rule with the Revised List of APHIS Select Agents is anticipated to be published in 2007.
- APHIS is encouraging comments to the proposed rule.
- All comments to the proposed rule will be reviewed by the SAL prior to the publication of the final rule.



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Questions?