APHIS’ Select Agent List Process

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

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
Rating Criteria Considerations

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

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.
Questions?